Structura seminar

- Clasificare reviste medicale si drumul parcurs de la redactarea articolului la publicare
- Cateva date de scientometrie
- *Necrotizing fasciitis in children in eastern Ontario: a case-control study*
- *A Randomized Trial of Rectal Indomethacin to Prevent Post-ERCP Pancreatitis*

Clasificarea revistelor medicale

- **Reviste cotate ISI [Institute for Scientific Information](cu factor de impact)**
- Din 2015 o noua baza de date extinsa **Emerging Sources Citation Index (ESCI)-** anticamera pentru obtinerea F.I
- **Reviste indexate in baze de date internationale (BDI)**
- Reviste cotate CNCSIS (A, B, B+, C, etc…)
- ATENTIE LA *“WASTED RESEARCH” “PUBLISH OR PERISH”*

JOURNAL SEARCH

EMERGING SOURCES CITATION INDEX - JOURNAL SEARCH

Title Word

SEARCH

ENTER A TITLE WORD, FULL TITLE, OR ISSN:

Title Word: *Enter as CELL or CELL**
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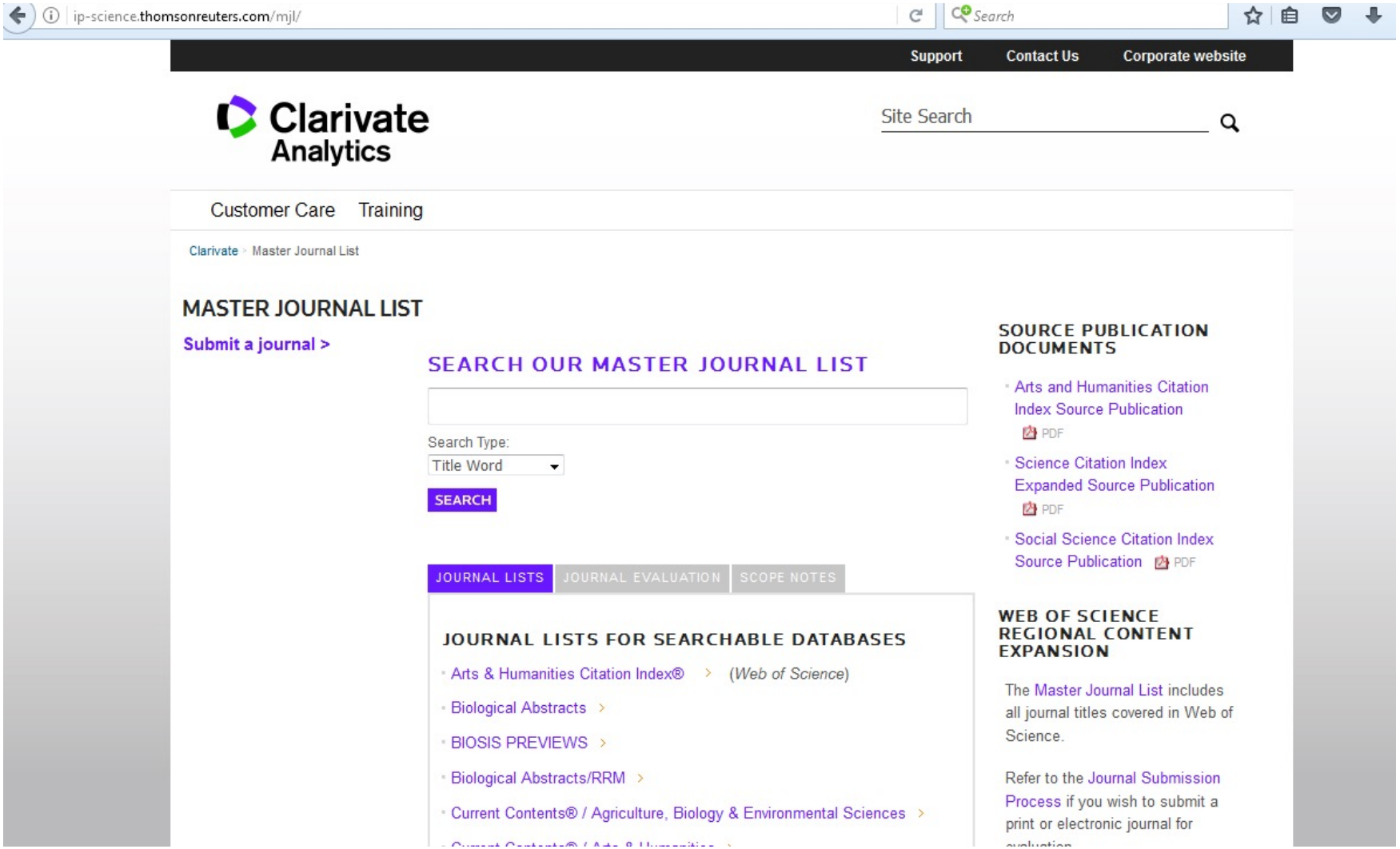
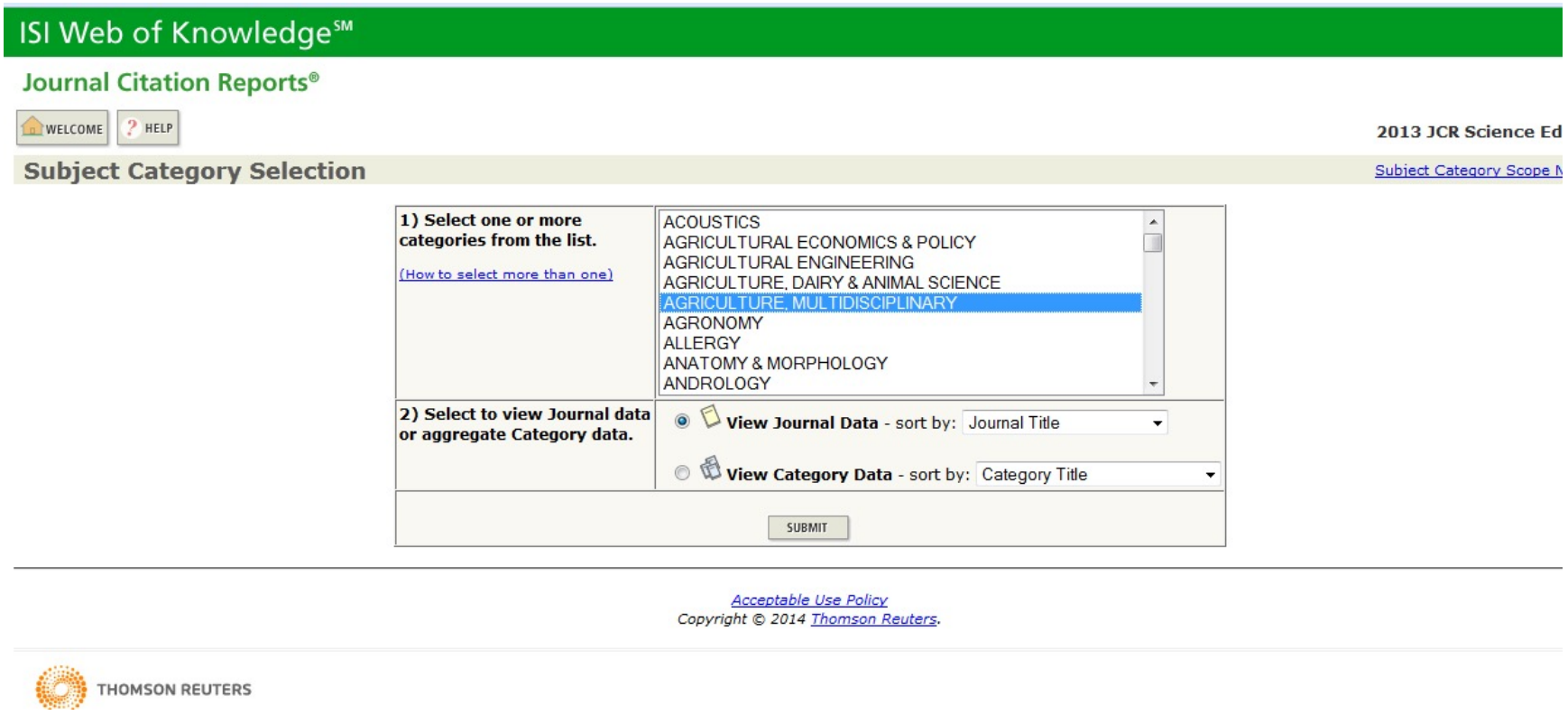


http://ip-science.thomsonreuters.com/mjl/

Drumul parcurs de la articol pana la publicare

- 1. Ne alegem revista
- 2.Consultam pagina de instructiuni pentru autor
- 3. Redactam articolul conform instructiunilor
- 4.Trimitem articolul
- 5.Primim raspunsul evaluarii (peer-reviewing)
- 6.Raspundem la evaluare
- 7 Articolul poate fi acceptat sau respins

1. Alegerea revistei



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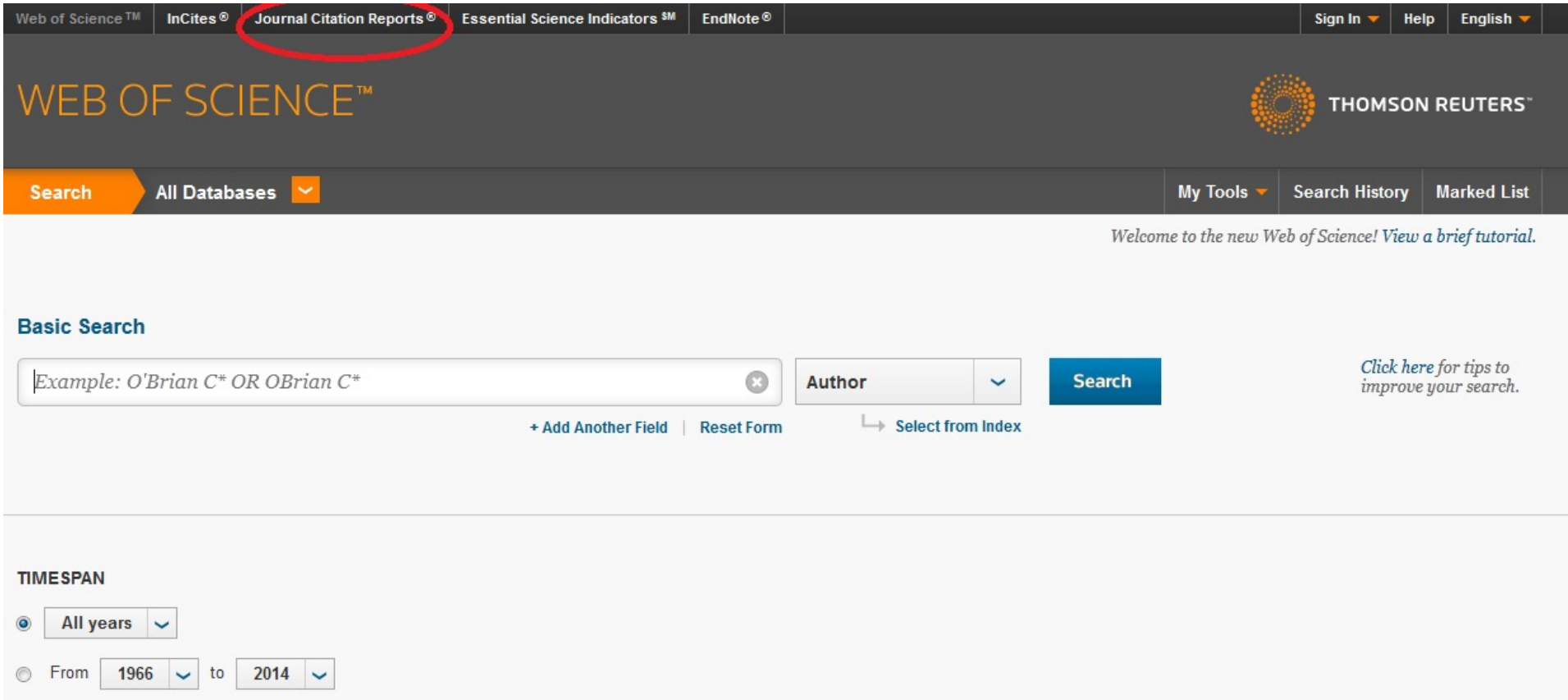
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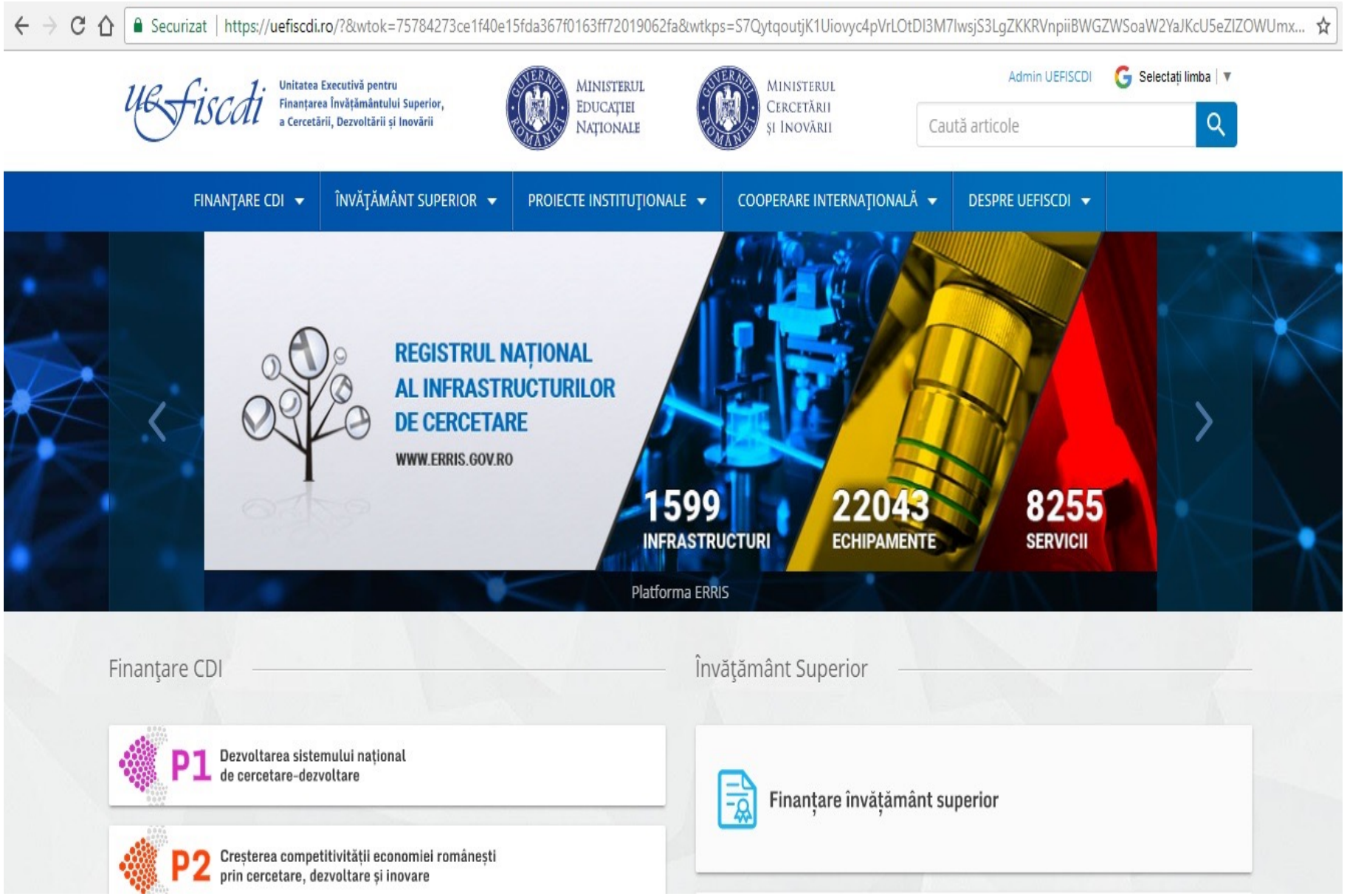
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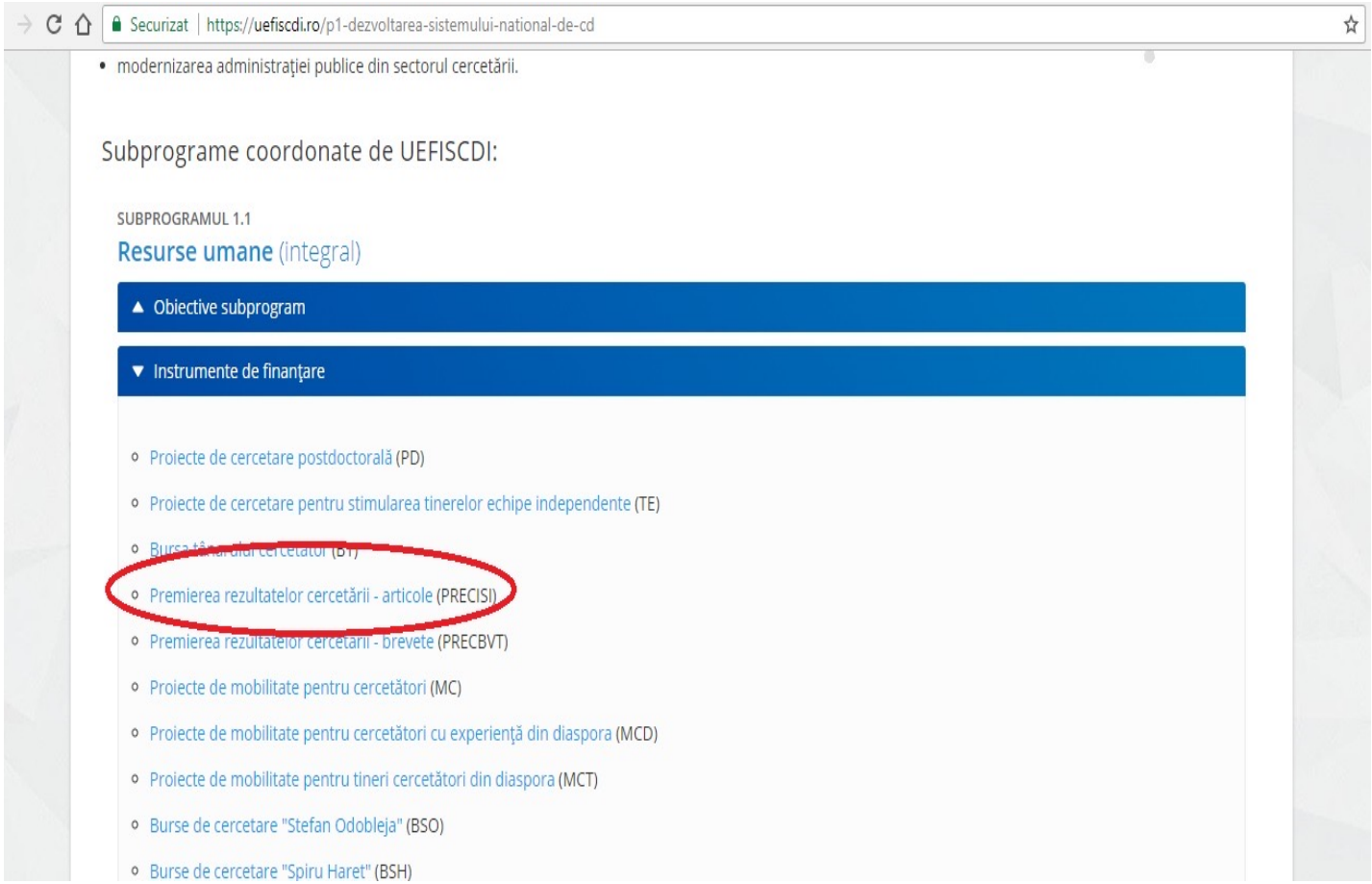
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▲ Obiective subprogram
▼ Instrumente de finanțare
Proiecte de cercetare postdoctorală (PD)
Proiecte de cercetare pentru stimularea tinerelor echipe independente (TE)
Premierea rezultatelor cercetării - articole (PRECISI)
Premierea rezultatelor cercetării - brevete (PRECBVT)
Proiecte de mobilitate pentru cercetători (MC)
Proiecte de mobilitate pentru cercetători cu experiență din diaspora (MCD)
Proiecte de mobilitate pentru tineri cercetători din diaspora (MCT)
Burse de cercetare "Stefan Odobleja" (BSO)
Burse de cercetare "Spiru Haret" (BSH)

FONDURI TOTALE

▲ Proces evaluare - Rezultate finale

▲ Lista propunerilor de proiect depuse

▼ Pachet de informaţii şi proces depunere

• Pachet de informaţii (aprobat prin Ordinul Ministrului Cercetării şi Inovării nr. 507/17.08.2017)

• Cererea de finanţare:

o Secţiunea 1: Informaţii despre articol şi autori
(se completează doar în platforma de depunere on-line, www.uefiscdi-direct.ro)

o Secţiunea 2: Validarea şi tipărirea Cererii de premiere

o Secţiunea 3: Incărcarea Cererii de premiere semnată şi scanată
(cererea de finanţare din secţiunea 2 tipărită, semnată de autori, scanată în format.pdf se încarcă în platforma de depunere on-line, www.uefiscdi-direct.ro)

o Secţiunea 4: Finalizarea cererii de premiere

Premiere articole publicate în anul 2017

• Pentru articolele publicate în reviste din Science Citation Index Expanded & Social Sciences Citation Index:

Lista revistelor încadrate pe subdomenii, ordonate în funcţie de factorul de impact al acestora (IF)

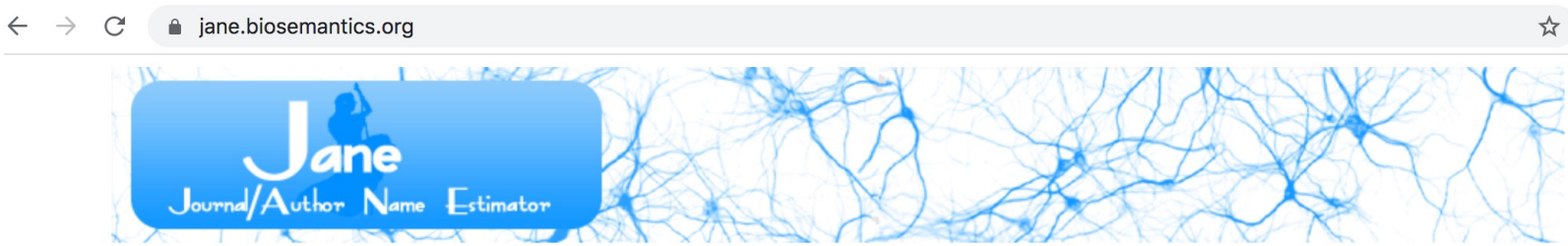
Lista revistelor încadrate pe subdomenii, ordonate în funcţie de scorul de influentă al acestora (AIS)

• Pentru articolele publicate în reviste indexate în Arts & Humanities Citation Index:

Lista revistelor indexate în Arts & Humanities Citation Index care au articole publicate în anul 2012 sau anterior

Lista revistelor incadrate pe subdomenii, ordonate descrescator in functie de factorul de impact al acestora (IF)
Indexate in Science Citation Index Expanded sau Social Sciences Citation Index

Index	Web of Science Category	Revista *(revistele marcate cu (*) au acelasi punctaj ca si revista anterioara)*	ISSN	Zona	Top
science	GASTROENTEROLOGY & HEPATOLOGY	J VIRAL HEPATITIS	1352-0504	1	15
science	GASTROENTEROLOGY & HEPATOLOGY	LIVER INT	1478-3223	1	16
science	GASTROENTEROLOGY & HEPATOLOGY	ALIMENT PHARM THER	0269-2813	1	17
science	GASTROENTEROLOGY & HEPATOLOGY	AM J PHYSIOL-GASTR L	0193-1857	1	18
science	GASTROENTEROLOGY & HEPATOLOGY	NEUROGASTROENT MOTIL	1350-1925	1	19
science	GASTROENTEROLOGY & HEPATOLOGY	LIVER TRANSPLANT	1527-6465	2	20
science	GASTROENTEROLOGY & HEPATOLOGY	CLIN LIVER DIS	1089-3261	2	21
science	GASTROENTEROLOGY & HEPATOLOGY	J CLIN GASTROENTEROL	0192-0790	2	22
science	GASTROENTEROLOGY & HEPATOLOGY	HELICOBACTER	1083-4389	2	23
science	GASTROENTEROLOGY & HEPATOLOGY	DIS COLON RECTUM	0012-3706	2	24
science	GASTROENTEROLOGY & HEPATOLOGY	DIGEST LIVER DIS	1590-8658	2	25
science	GASTROENTEROLOGY & HEPATOLOGY	J GASTROEN HEPATOL	0815-9319	2	26
science	GASTROENTEROLOGY & HEPATOLOGY	J GASTROINTEST SURG	1091-255X	2	27
science	GASTROENTEROLOGY & HEPATOLOGY	HEPATOL INT	1936-0533	2	28
science	GASTROENTEROLOGY & HEPATOLOGY	GASTROENTEROL CLIN N	0889-8553	2	29
science	GASTROENTEROLOGY & HEPATOLOGY	COLORECTAL DIS	1462-8910	2	30
science	GASTROENTEROLOGY & HEPATOLOGY	J CROHNS COLITIS	1873-9946	2	31
science	GASTROENTEROLOGY & HEPATOLOGY	WORLD J GASTROENTERO	1007-9327	2	32
science	GASTROENTEROLOGY & HEPATOLOGY	BEST PRACT RES CL GA	1521-6918	2	33
science	GASTROENTEROLOGY & HEPATOLOGY	BMC GASTROENTEROL	1471-230X	2	34
science	GASTROENTEROLOGY & HEPATOLOGY	GASTRIC CANCER	1436-3291	2	35



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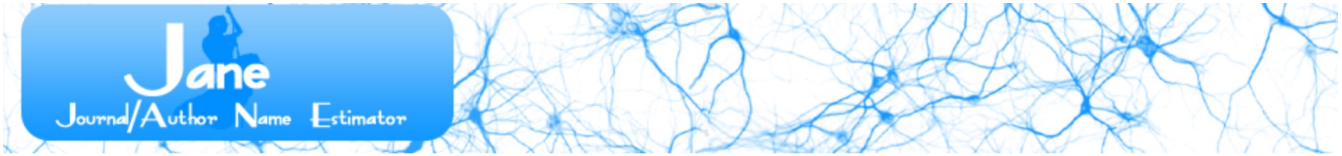

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Background: Systemic sclerosis (Ssc) is an autoimmune disease with incomplete known physiopathology. There is a high number of candidate proteomic biomarkers for Ssc that have not yet been confirmed on independent Ssc cohorts. The aim of the study was to confirm circulating S100A6, calumenin, and cytohesin 2 as biomarkers for Ssc. Methods: 53 Ssc patients and 26 age- and gender-matched controls were included. Serum S100A6, calumenin, and cytohesin 2 were evaluated with commercial ELISA kits. Associations between serum expression and clinical Ssc characteristics were evaluated. Results: Serum calumenin, S100A6, and cytohesin 2 were higher in Ssc patients compared to controls. Calumenin associated with extensive cutaneous fibrosis, frequency of Raynaud phenomenon, and low complement level, and had a tendency to be higher in Ssc patients with pulmonary fibrosis. S100A6 correlated with the number of active digital ulcers. Serum cytohesin 2 levels were higher in patients with teleangiectasia and associated with pulmonary artery pressure. Conclusions: Serum calumenin, S100A6, and cytohesin 2 were confirmed as biomarkers on an independent group of Ssc patients. Calumenin had the best predictive capacity for cutaneous Ssc manifestations. Future studies are needed to evaluate the prognostic value of these biomarkers and evaluate them as possible therapeutic targets

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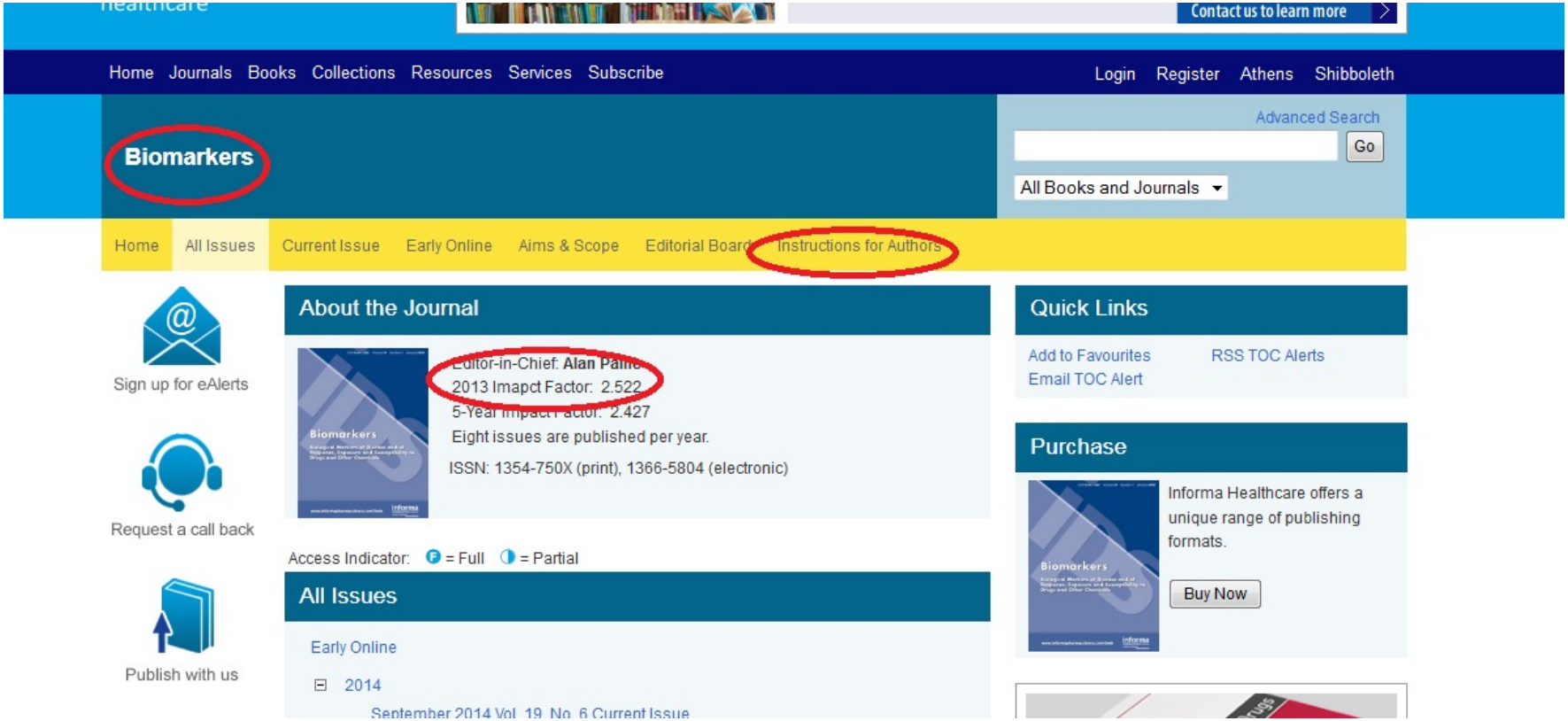
	The Journal of rheumatology Medline-indexed	1.0	Show articles
	Annals of the rheumatic diseases Medline-indexed	3.0	Show articles
	Rheumatology international Medline-indexed	0.5	Show articles
	Seminars in arthritis and rheumatism Medline-indexed	1.4	Show articles
	PloS one High-quality open access Medline-indexed PMC	1.1	Show articles
	Arthritis & rheumatology (Hoboken, N.J.) Medline-indexed	1.9	Show articles
	International journal of rheumatic diseases Medline-indexed	0.5	Show articles
	Rheumatology (Oxford, England) Medline-indexed PMC	1.5	Show articles
	Journal of the European Academy of Dermatology and Venereology : JEADV Medline-indexed	0.9	Show articles
	Scientific reports High-quality open access Medline-indexed PMC	1.9	Show articles
	Clinical laboratory Medline-indexed	0.2	Show articles
	Clinical chemistry and laboratory medicine Medline-indexed	0.6	Show articles
	Digestive diseases and sciences Medline-indexed	0.7	Show articles
	Journal of clinical immunology Medline-indexed	1.0	Show articles
	Romanian journal of internal medicine = Revue roumaine de medecine interne High-quality open access Medline-indexed		Show articles
	Experimental dermatology Medline-indexed	0.8	Show articles
	The British journal of dermatology Medline-indexed	1.4	Show articles
	Arthritis research & therapy High-quality open access Medline-indexed PMC	1.4	Show articles
	Biomedicines High-quality open access PMC		Show articles
	Best practice & research. Clinical rheumatology Medline-indexed	1.3	Show articles

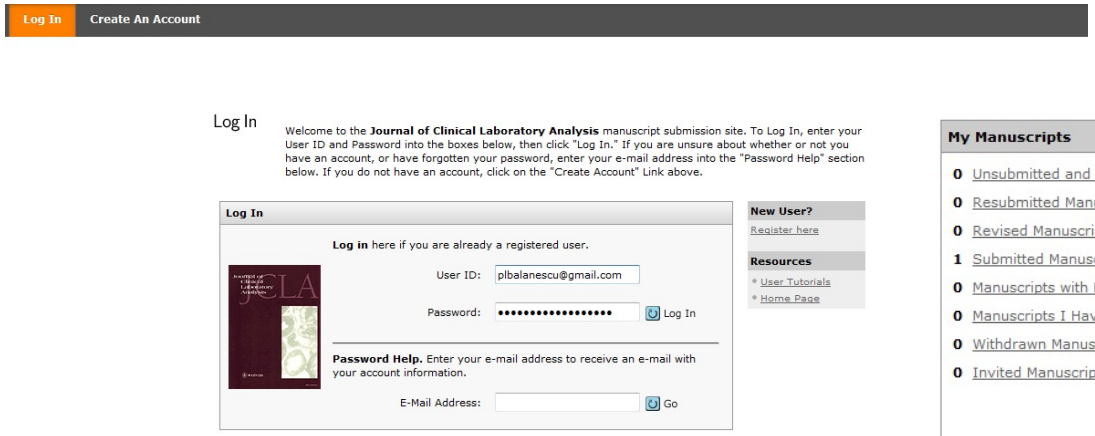
2. Consultam instructiuni pentru autori

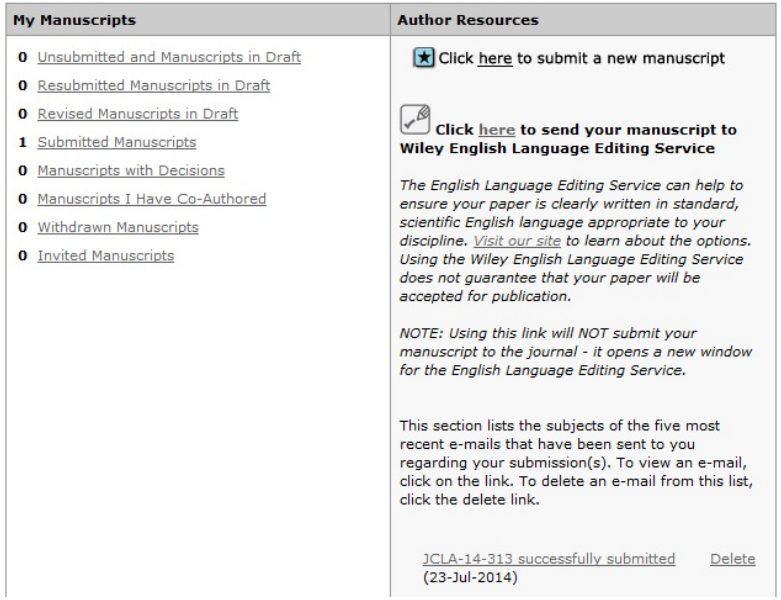


Biomarkers
Instructions for Authors

3.Redactarea si trimiterea articolului

- Majoritatea au platforma online de depunere articol





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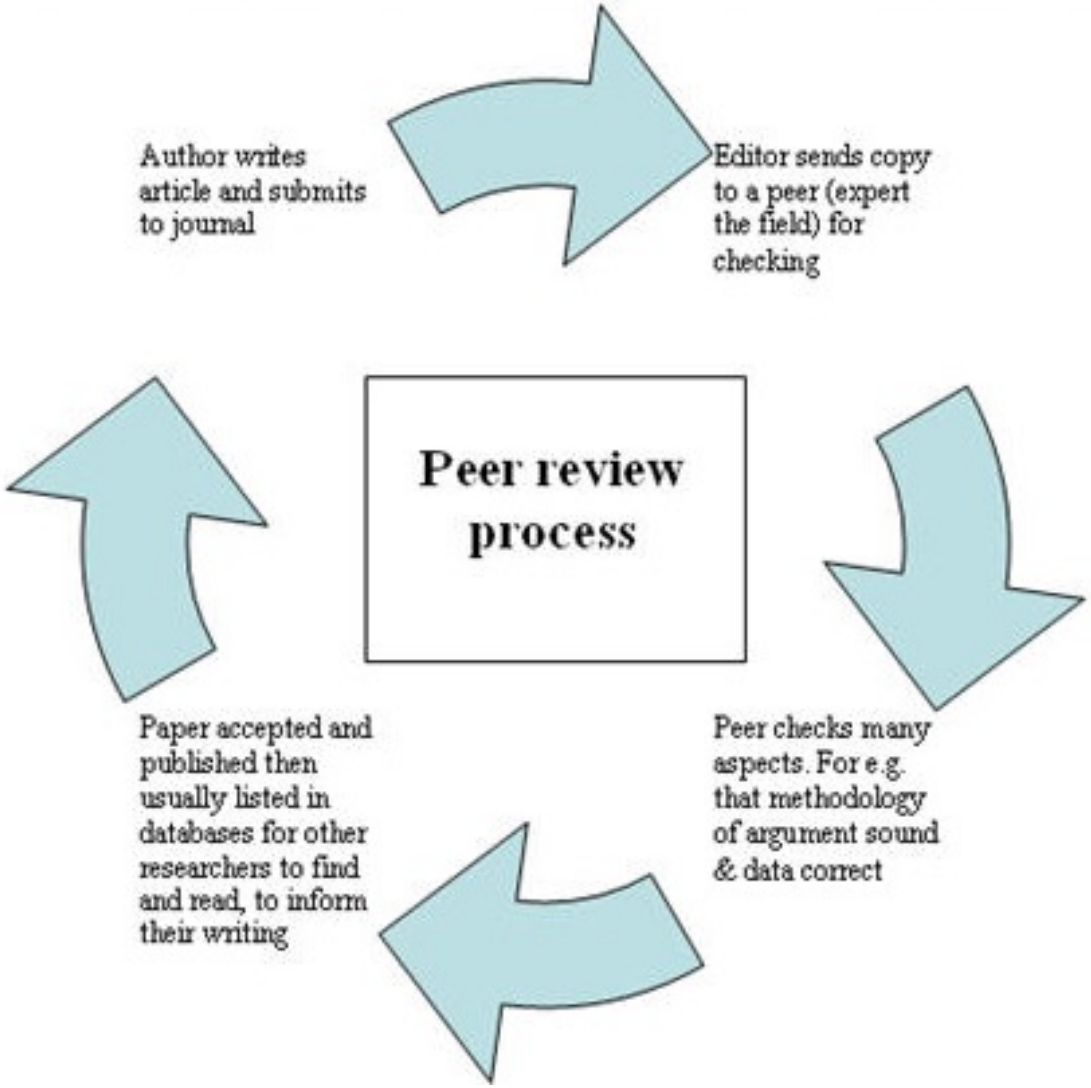

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Avantajele publicarii

- Prestigiu, vizibilitate nationala si internationala
- Avansare profesionala (obtinerea titlului de doctor in stiinte)
- Poti la randul tau sa faci activitate de peer-reviewer pentru articole, propuneri de proiecte de cercetare
- Dezvoltarea si imbunatatirea rigorii stiintifice
- Dezvoltarea simtului critic

Cum se evalueaza impactul cercetarii unui cercetator?

- INDICELE Hirsch-indice de citare
- Poate fi calculat in Google Scholar sau WoS Core Collection
- Indice scientometric
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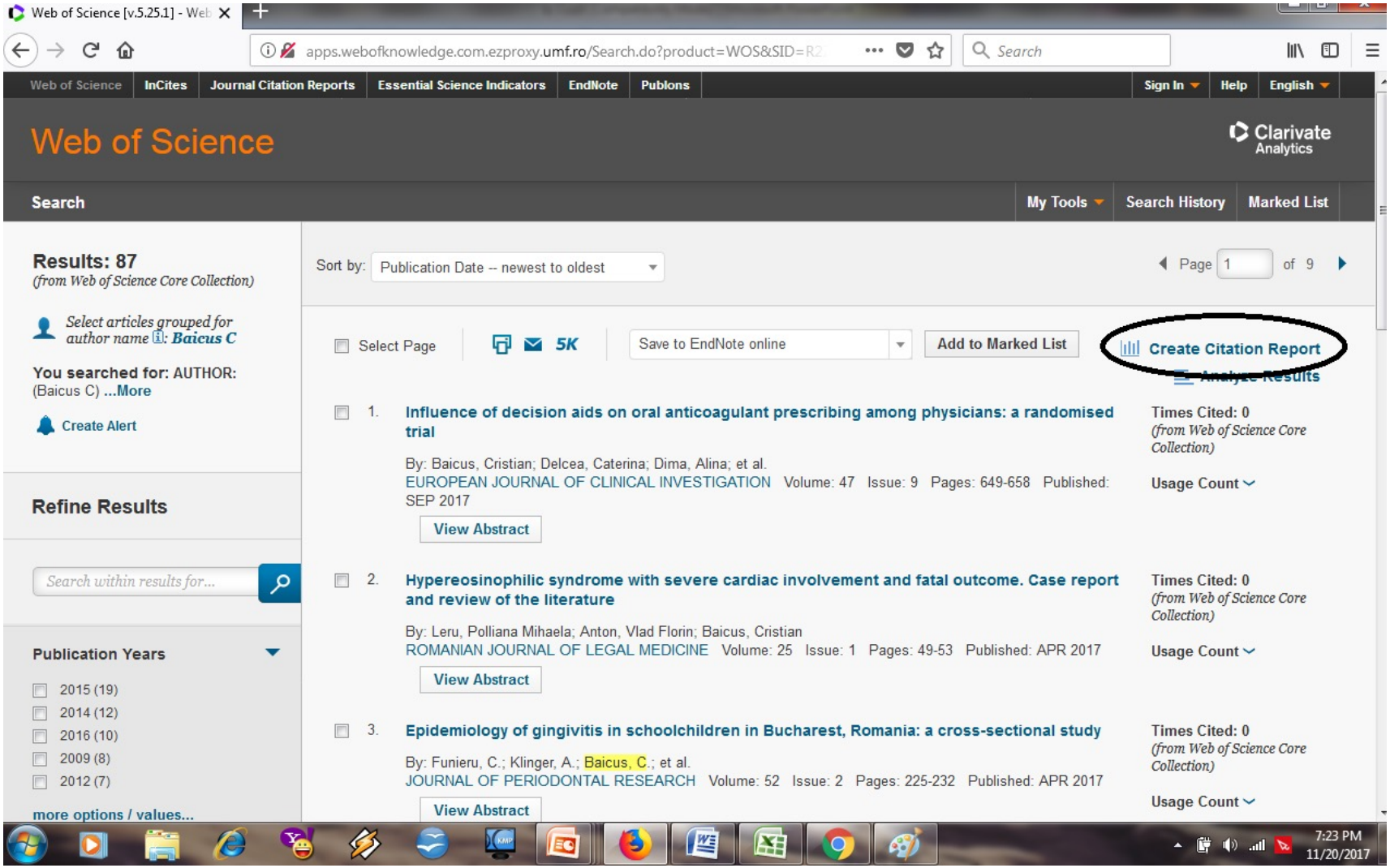
- Art 3: 3 citari
- Art 4: are 1 citare
- Art 5: 0 citari
- Are Indice H de 3 (are cel putin 3 articole cu 3 citari)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By: Baicus, Cristian; Delcea, Caterina; Dima, Alina; et al.
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3. Epidemiology of gingivitis in schoolchildren in Bucharest, Romania: a cross-sectional study
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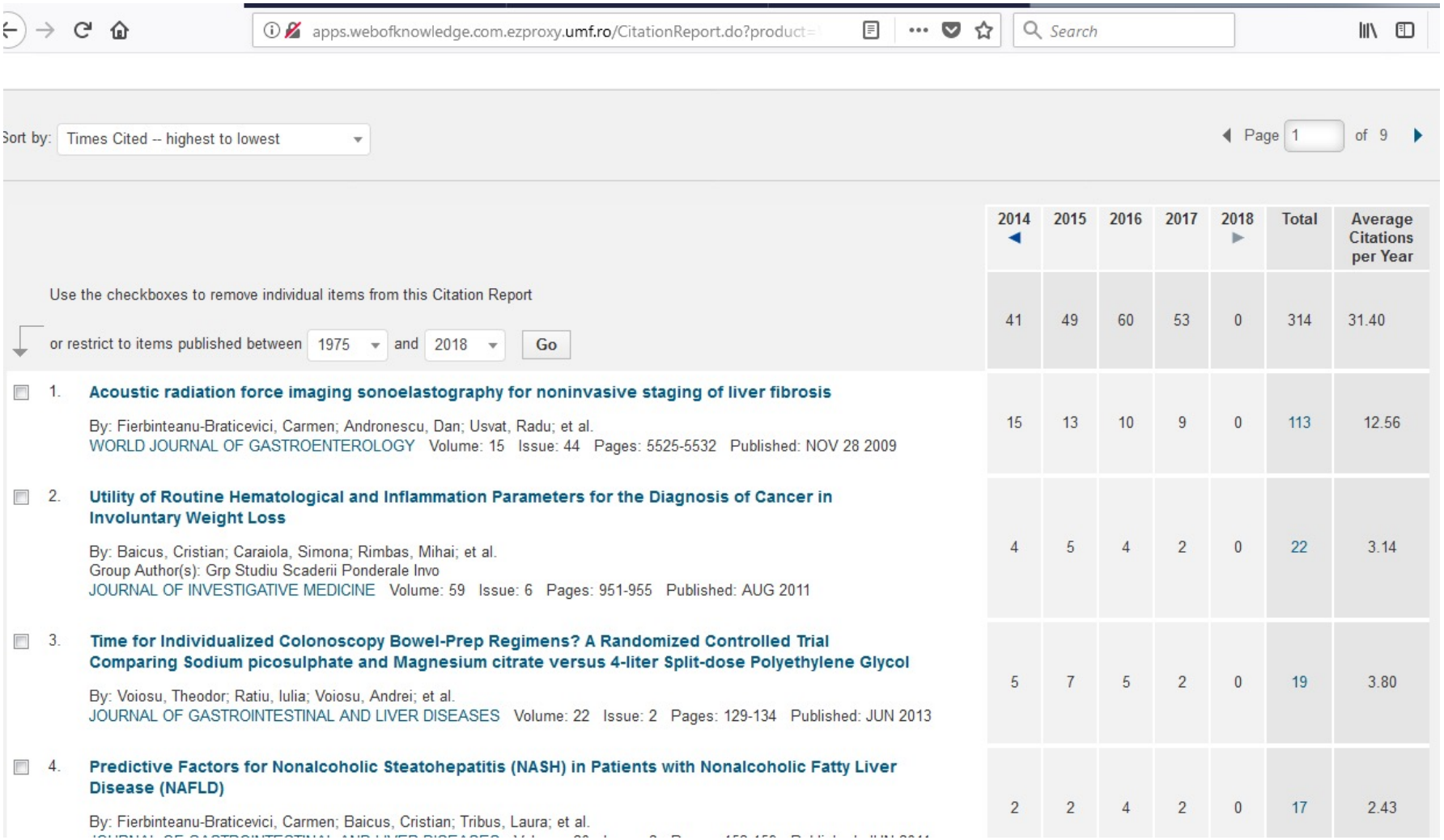
289

Citing articles
303

Without self citations
287

Sum of Times Cited per Year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By: Fierbinteanu-Braticevici, Carmen; Andronescu, Dan; Usvat, Radu; et al.
WORLD JOURNAL OF GASTROENTEROLOGY Volume: 15 Issue: 44 Pages: 5525-5532 Published: NOV 28 2009
15 13 10 9 0 113 12.56
2. Utility of Routine Hematological and Inflammation Parameters for the Diagnosis of Cancer in Involuntary Weight Loss
By: Baicus, Cristian; Caraiola, Simona; Rimbas, Mihai; et al.
Group Author(s): Grp Studiu Scaderii Ponderale Invo
JOURNAL OF INVESTIGATIVE MEDICINE Volume: 59 Issue: 6 Pages: 951-955 Published: AUG 2011
4 5 4 2 0 22 3.14
3. Time for Individualized Colonoscopy Bowel-Prep Regimens? A Randomized Controlled Trial Comparing Sodium picosulphate and Magnesium citrate versus 4-liter Split-dose Polyethylene Glycol
By: Voiosu, Theodor; Ratiu, Iulia; Voiosu, Andrei; et al.
JOURNAL OF GASTROINTESTINAL AND LIVER DISEASES Volume: 22 Issue: 2 Pages: 129-134 Published: JUN 2013
5 7 5 2 0 19 3.80
4. Predictive Factors for Nonalcoholic Steatohepatitis (NASH) in Patients with Nonalcoholic Fatty Liver Disease (NAFLD)
By: Fierbinteanu-Braticevici, Carmen; Baicus, Cristian; Tribus, Laura; et al.
2 2 4 2 0 17 2.43

Cum reusim sa publicam?

- Idee intr-un anumit domeniu
- Citind multe articole pe tema respectiva
- Realizarea unui protcol de studiu/tip de studiu
- **SCRIEM, SCRIEM, SCRIEM-trimitem** articole reviste BDI, locale, ESCI!
- **+/- Obtinere suport financiar**
- **Trimitand catre publicare articolul, imbunatatindu-l dupa procesul de peer-reviewing**

Necrotizing fasciitis in children in eastern Ontario: a case–control study

Tauyee Hsieh,[*] Lindy M. Samson,[†] Mona Jabbour,[†]
Martin H. Osmond[†]

Research

Recherche

1. Obiectivele?
2. Tipul de studiu?
3. Abordare-retrospectiva/prospectiva?

De ce?

tween necrotizing fasciitis and cellulitis is essential for early and effective management.

The objectives of our study were to document potential increases in the frequency of necrotizing fasciitis at a tertiary care pediatric hospital in Ontario, and to attempt to determine the unique clinical and laboratory features that distinguish necrotizing fasciitis from that of cellulitis.

We conducted a retrospective case–control study of all children with necrotizing fasciitis presenting to the Children's Hospital of Eastern Ontario (CHEO), in Ottawa. CHEO is a tertiary care hospital and the only pediatric inpatient facility in the city. Serving eastern Ontario and western Quebec, it has a catchment area of 1.5 million people and receives about 49 000 patient visits per year through the emergency department. The study design was approved by the CHEO Research Ethics Committee.

The charts of all children with necrotizing fasciitis under 18 years of age admitted to CHEO between June 1, 1983, and May 31, 1999, were reviewed. Necrotizing fasciitis was defined as a

4. Populatia studiata?

- Cazurile/martorii
- Lotul martor bine ales functie de obiective?

5. Cum au fost definite grupurile?

Cases were identified by searching the hospital's discharge diagnosis database using the International Classification of Diseases, 9th revision (ICD-9) code corresponding to the diagnosis of necrotizing fasciitis. To ensure that no cases were missed, all charts identified with the ICD-9 codes for myositis, gangrene, gas gangrene and erysipelas were also reviewed. Charts of children with group A β-hemolytic *Streptococcus* cultured from sterile sites during the same study period were also reviewed.

Control subjects were children under 18 years of age admitted and treated at CHEO for cellulitis. They were identified by ICD-9 codes based on the discharge diagnosis recorded by the attending physician. Control subjects were randomly selected and matched to the case subjects first by date of admission and then by closest date of birth (first by day, then by month and, if necessary, by year). Three control subjects were identified for every case subject.

6. Care au fost variabilele masurate?

data. Age, sex, demographic information, diagnosis, site of infection, presenting signs and symptoms, comorbidities, blood values, culture results, treatment and outcome were recorded. Presenting signs and symptoms included focal swelling, focal erythema, focal pain, focal splinting, significant tenderness, generalized erythematous rash and "toxic appearance," as described by the emergency physician. If no record was made of these features they were assumed to be absent. Focal splinting was defined as refusal to use the affected part of the body. Significant tenderness was defined as substantial pain, as recorded on examination by the physician. Blood values obtained at presentation included the following: hemoglobin, white blood cell count and differential, platelet count, erythrocyte sedimentation rate, alanine aminotransferase (ALT) level and creatinine kinase level. Outcome fell into 1 of 4 categories: complete recovery, temporary disability requiring rehabilitation or further follow-up, permanent disability, or death.

De ce credeti ca a fost necesar ca datele sa fie extrase de aceeasi persoana?

De ce credeti ca a fost necesar ca evaluarea datelor sa fie facuta in orb si independent?

Variable	Case subjects *n = 8*	Control subjects *n = 24*	*p* value
Mean age (and range), yr	5.00 (2.10–13.08)	4.62 (0.44–14.6)	0.69
Male sex, no. of children	3	16	0.22
Signs and symptoms, no. of children			
Generalized erythematous rash	4	2	0.02
Toxic appearance	4	1	< 0.001
Focal swelling	7	17	0.64
Focal erythema	7	24	0.25
Focal pain	7	7	0.10
Focal splinting	3	3	0.15
Significant tenderness	3	3	0.15
Vital signs			
Mean heart rate (and range), beats/min	136.25 (80–156)	121.42 (80–186)	0.10
Mean respiratory rate (and range), breaths/min	31.50 (20–48)	25.42 (18–38)	0.02
Mean systolic blood pressure (and range), mm Hg	104.88 (90–120)	*n = 19* 106.47 (86–130)	0.79
Mean diastolic blood pressure (and range), mm Hg	55.63 (40–80)	*n = 19* 64.53 (47–93)	0.07
Mean temperature (and range), °C	38.7 (38.0–39.4)	37.8 (36.1–40.7)	0.006
No. with history of fever	8	10	0.004

Cum definim tabelul contingenta?

		GRUPURI STUDIU		
		CAZURI (Fasceita-DA)	MARTORI (Fasceita-NU)-celulita	
FACTOR RISC	DA (EXPUSI)	a	b	a+b
	NU (NEEXPUSI)	c	d	c+d
		a+c	b+d	

Cota la cazuri=a/c

Cota la martori=b/d

OR=[a/c]/[b/d] =ad/bc

Spre deosebire de cohorta, se calculeaza cotele (odds) factorului de risc la cazuri respectiv martori!!!!!

Variable	Case subjects $n = 8$	Control subjects $n = 24$	p value
Mean age (and range), yr	5.00 (2.10–13.08)	4.62 (0.44–14.6)	0.69
Male sex, no. of children	3	16	0.22
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Focal pain	7	7	0.10
Focal splinting	3	3	0.15
Significant tenderness	3	3	0.15

OR pentru rash eritematos generalizat?
OR Aspect toxic?
OR Edem local?
OR Eritem local?
OR Imobilizare locala?
OR Sensibilitate semnificativa?

(control subjects) in eastern Ontario

Variable	Case subjects *n = 8*	Control subjects *n = 24*	*p* value
Blood values			
Mean white blood cell count (WBC) (and range), x 10^9/L	17.12 (3.14–40.5)	13.22 (5.64–23.5)	0.53
No. with high WBC*	5	6	0.09
No. with low WBC†	2	0	0.06
Mean hemoglobin level (and range), g/L	117.63 (95–141)	121.33 (101–143)	0.47
Mean platelet count (and range), x 10^9/L	194.00 (15–375)	299.33 (157–458)	0.03
No. with low platelet count‡	2	0	0.06
Comorbidity			
Varicella infection	4	7	0.40
Surgery	1	1	0.44
Trauma	2	12	0.41
Culture result, no. of children			
Group A β-hemolytic *Streptococcus*	7	4	< 0.001
Staphylococcus aureus	1	5	1
	n = 7	*n = 23*	
Positive blood culture	3	1	0.04
Outcome			
No. admitted to ICU	7	0	
Mean length of stay in ICU (and range), d	4.38 (0–11)	0 (0–0)	< 0.001
Mean total length of stay (and range), d	23.38 (17–38)	3.92 (1–14)	< 0.001
No. with temporary disability	7	2	< 0.001

Note: ICU = intensive care unit.
*High WBC = > 15.5 x 10^9/L.
†Low WBC = < 5.5 x 10^9/L.

7. Care sunt concluziile studiului?
8. Care au fost limitarile studiului?
9. De ce s-a optat pentru un design de studiu caz-martor?
10. Cum ati continua studiul? Ce alt studiu ati initia plecand de la concluziile prezentului studiu?

a secondary skin infection and a toxic appearance.

Given the retrospective nature of our study, it was limited because of missing data in some of the charts and a lack of standardization in the parameters reviewed. Because of the small number of cases of necrotizing fasciitis identified, potentially significant features may not have been identified.

In summary, we found that the number of cases of necrotizing fasciitis has increased over the past 16 years in the Ottawa region. Factors that help distinguish necrotizing fasciitis from cellulitis include a generalized erythematous rash, toxic appearance, fever and low platelet count. Further research of this disease and its presenting signs and symptoms, perhaps in the form of a large multicentre study, are needed to help clinicians with the early identification and treatment of these cases.

ORIGINAL ARTICLE

A Randomized Trial of Rectal Indomethacin to Prevent Post-ERCP Pancreatitis

B. Joseph Elmunzer, M.D., James M. Scheiman, M.D., Glen A. Lehman, M.D., Amitabh Chak, M.D., Patrick Mosler, M.D., Ph.D., Peter D.R. Higgins, M.D., Ph.D., Rodney A. Hayward, M.D., Joseph Romagnuolo, M.D., Grace H. Elta, M.D., Stuart Sherman, M.D., Akbar K. Waljee, M.D., Aparna Repaka, M.D., Matthew R. Atkinson, M.D., Gregory A. Cote, M.D., Richard S. Kwon, M.D., Lee McHenry, M.D., Cyrus R. Piraka, M.D., Erik J. Wamsteker, M.D., James L. Watkins, M.D., Sheryl J. Korsnes, M.A., Suzette E. Schmidt, B.S.N., C.C.R.P., Sarah M. Turner, B.S., Sylvia Nicholson, C.C.R.C., and Evan L. Fogel, M.D., for the U.S. Cooperative for Outcomes Research in Endoscopy (USCORE)

- Tipul de studiu?
- -Observational? Interventional?
- Obiectivele?
- Care a fost populatia studiata?
- Care au fost efectele studiate?

BACKGROUND

Preliminary research suggests that rectally administered nonsteroidal antiinflammatory drugs may reduce the incidence of pancreatitis after endoscopic retrograde cholangiopancreatography (ERCP).

METHODS

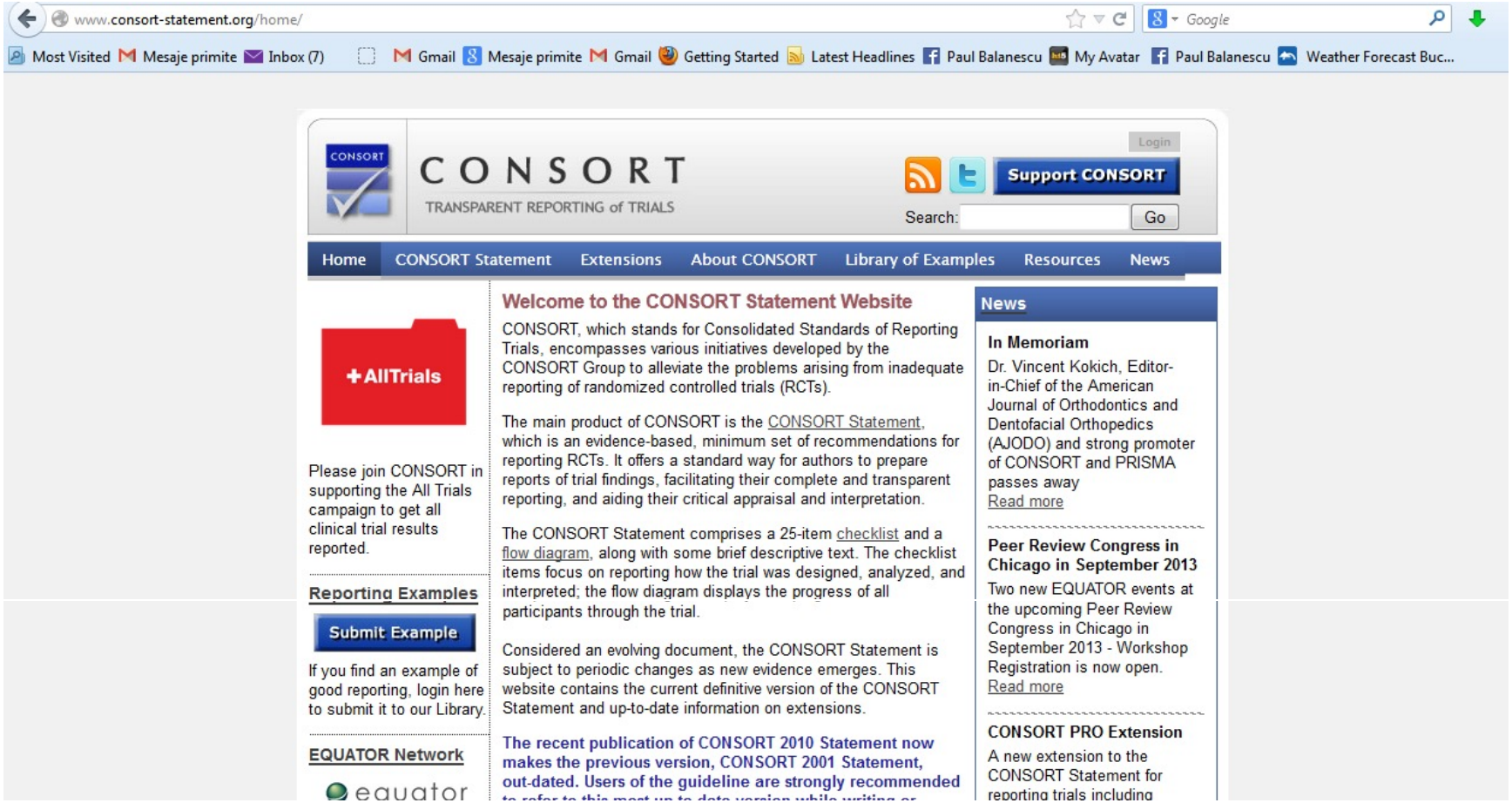
In this multicenter, randomized, placebo-controlled, double-blind clinical trial, we assigned patients at elevated risk for post-ERCP pancreatitis to receive a single dose of rectal indomethacin or placebo immediately after ERCP. Patients were determined to be at high risk on the basis of validated patient- and procedure-related risk factors. The primary outcome was post-ERCP pancreatitis, which was defined as new upper abdominal pain, an elevation in pancreatic enzymes to at least three times the upper limit of the normal range 24 hours after the procedure, and hospitalization for at least 2 nights.

RESULTS

A total of 602 patients were enrolled and completed follow-up. The majority of patients (82%) had a clinical suspicion of sphincter of Oddi dysfunction. Post-ERCP pancreatitis developed in 27 of 295 patients (9.2%) in the indomethacin group and in 52 of 307 patients (16.9%) in the placebo group ($P=0.005$). Moderate-to-severe pancreatitis developed in 13 patients (4.4%) in the indomethacin group and in 27 patients (8.8%) in the placebo group ($P=0.03$).

CONCLUSIONS

Among patients at high risk for post-ERCP pancreatitis, rectal indomethacin significantly reduced the incidence of the condition. (Funded by the National Institutes of Health; ClinicalTrials.gov number, NCT00820612.)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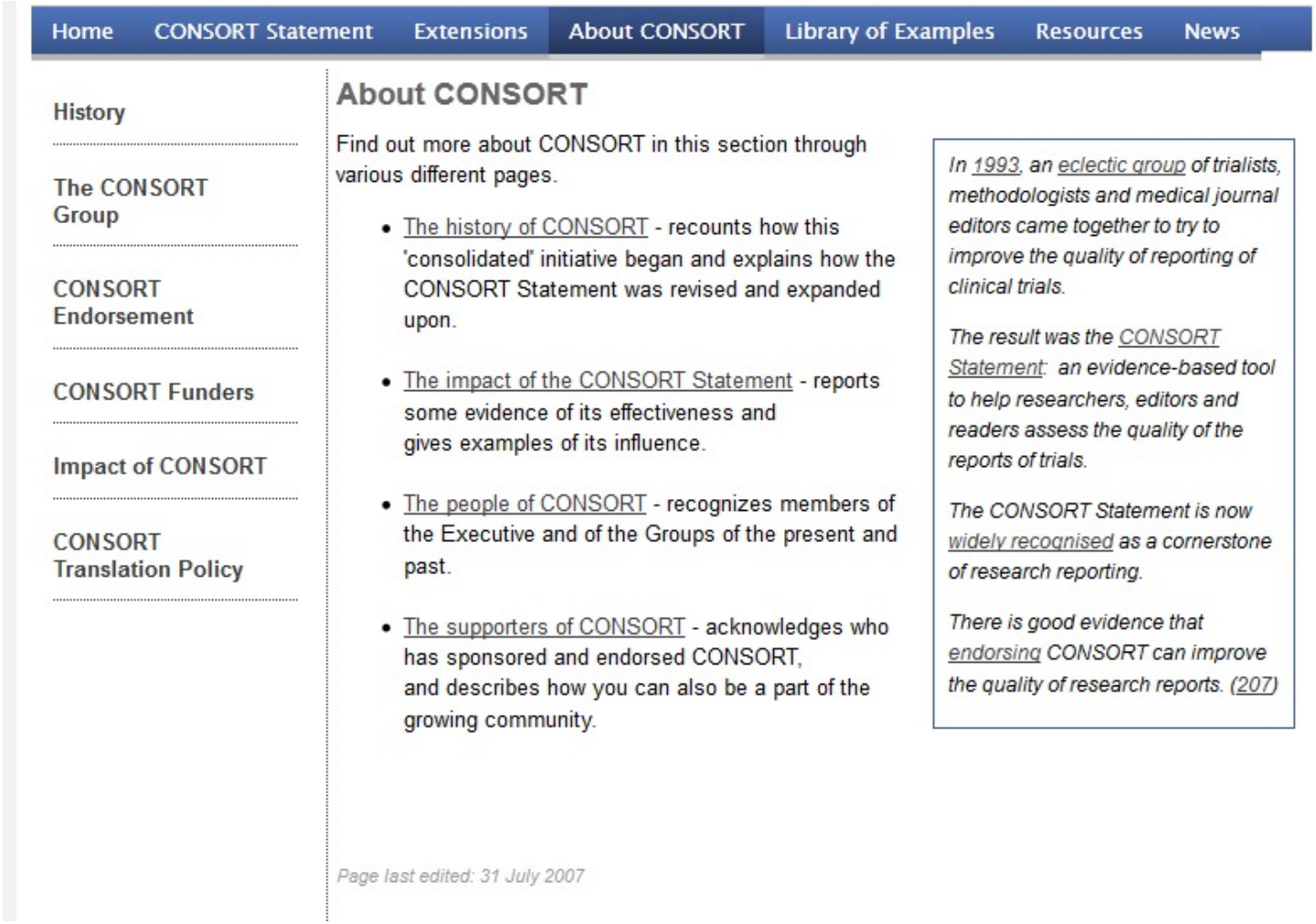
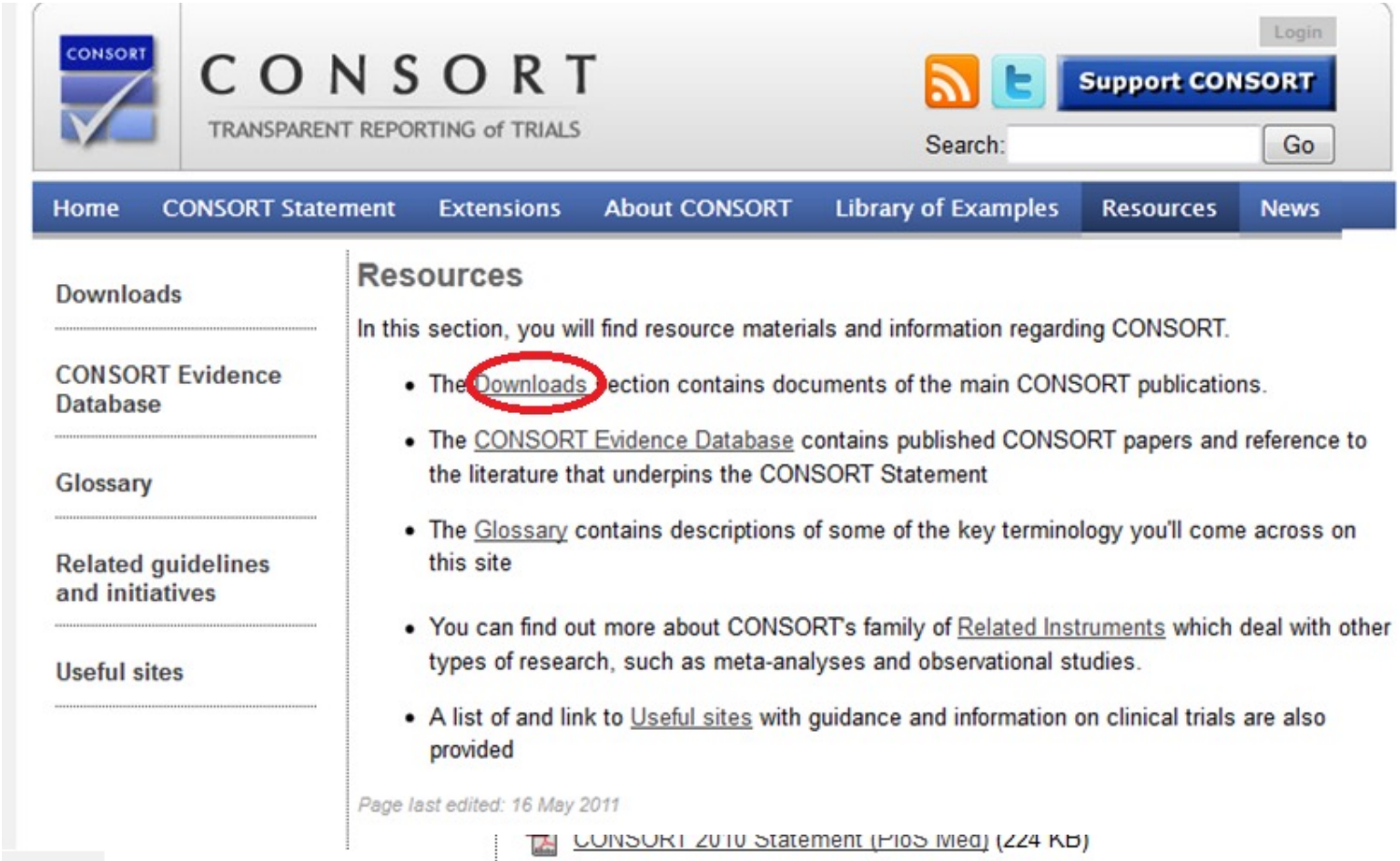
EQUATOR Network
equator
Welcome to the CONSORT Statement Website
CONSORT, which stands for Consolidated Standards of Reporting Trials, encompasses various initiatives developed by the CONSORT Group to alleviate the problems arising from inadequate reporting of randomized controlled trials (RCTs).
The main product of CONSORT is the CONSORT Statement, which is an evidence-based, minimum set of recommendations for reporting RCTs. It offers a standard way for authors to prepare reports of trial findings, facilitating their complete and transparent reporting, and aiding their critical appraisal and interpretation.
The CONSORT Statement comprises a 25-item checklist and a flow diagram, along with some brief descriptive text. The checklist items focus on reporting how the trial was designed, analyzed, and interpreted; the flow diagram displays the progress of all participants through the trial.
Considered an evolving document, the CONSORT Statement is subject to periodic changes as new evidence emerges. This website contains the current definitive version of the CONSORT Statement and up-to-date information on extensions.
The recent publication of CONSORT 2010 Statement now makes the previous version, CONSORT 2001 Statement, out-dated. Users of the guideline are strongly recommended
News
In Memoriam
Dr. Vincent Kokich, Editor-in-Chief of the American Journal of Orthodontics and Dentofacial Orthopedics (AJODO) and strong promoter of CONSORT and PRISMA passes away
Read more
Peer Review Congress in Chicago in September 2013
Two new EQUATOR events at the upcoming Peer Review Congress in Chicago in September 2013 - Workshop Registration is now open.
Read more
CONSORT PRO Extension
A new extension to the CONSORT Statement for reporting trials including



http://www.consort-statement.org/



CONSORT 2010 Statement (PloS Med) (224 KB)

CONSORT 2010 E&E (BMJ) (652 KB)

CONSORT 2010 E&E (J Clin Epidemiol) (563 KB)

CONSORT 2010 Statement (Journal of Pharmacology and Pharmacotherapeutics).pdf (74 KB)

CONSORT 2010 checklist (pdf) (52 KB)

CONSORT 2010 checklist (doc) (222 KB)

CONSORT 2010 flow diagram (pdf) (55 KB)

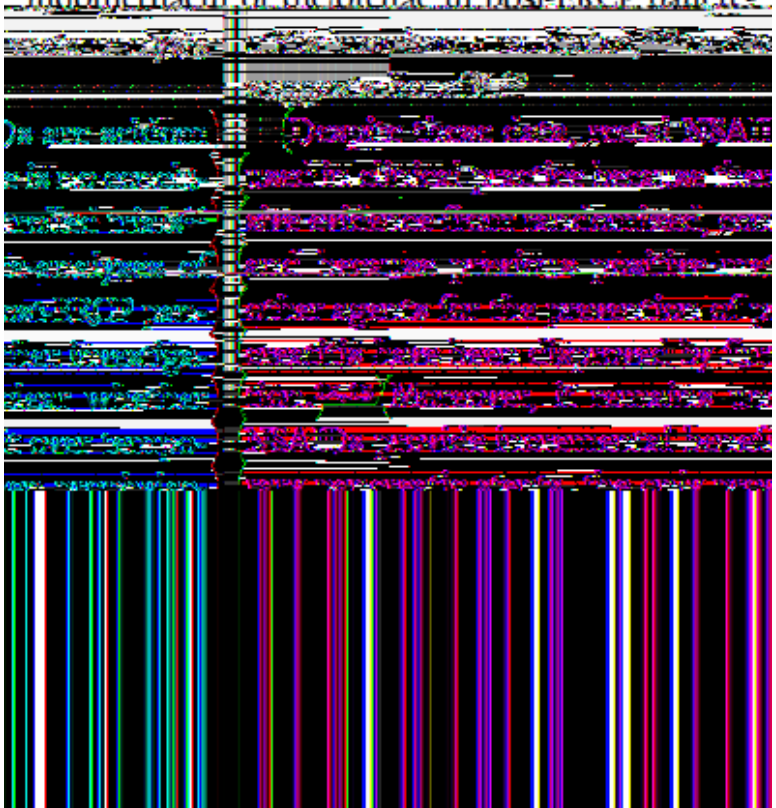
CONSORT 2010 flow diagram (doc) (32 KB)

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page N
Title and abstract			
	1a	Identification as a randomised trial in the title	
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	
	2b	Specific objectives or hypotheses	
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	
	4b	Settings and locations where the data were collected	
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
[illegible]	[illegible]	[illegible]	
[illegible]	[illegible]	[illegible]	
[illegible]	[illegible]	[illegible]	
[illegible]	[illegible]	[illegible]	
[illegible]	[illegible]	[illegible]	
[illegible]	[illegible]	[illegible]	

Title and abstract		
	1a	Identification as a randomised trial in the title
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)
Introduction		
Background and objectives	2a	Scientific background and explanation of rationale
	2b	Specific objectives or hypotheses

pathogenesis of acute pancreatitis.[4,5] NSAIDs are inexpensive and easily administered and have a favorable risk profile when given as a single dose, making them an attractive option in the prevention of post-ERCP pancreatitis. Preliminary studies evaluating the protective effects of single-dose rectal indomethacin or diclofenac in post-ERCP pancre-



De ce credeti ca este important ca titlul sa contina cuvantul “studiu clinic randomizat”? (cerinta 1a-randomised trial?)

Methods		
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons
Participants	4a	Eligibility criteria for participants
	4b	Settings and locations where the data were collected
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed
	6b	Any changes to trial outcomes after the trial commenced, with reasons
Sample size	7a	How sample size was determined
	7b	When applicable, explanation of any interim analyses and stopping guidelines
Randomisation:		
Sequence generation	8a	Method used to generate the random allocation sequence
	8b	Type of randomisation; details of any restriction (such as blocking and block size)
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions

The inclusion criteria selected patients with an elevated baseline risk of post-ERCP pancreatitis on the basis of prospectively validated patient- and procedure-related independent risk factors.[17] Patients were eligible if they met one or more of the following major criteria: clinical suspicion of sphincter of Oddi dysfunction (as defined in the Supplementary Appendix, available at NEJM.org), a history of post-ERCP pancreatitis, pancreatic sphincterotomy, precut sphincterotomy (a procedure performed to facilitate biliary access when standard cannulation techniques are unsuccessful), more than eight cannulation attempts (as determined by the endoscopist), pneumatic dilatation of an intact biliary sphincter, or ampullectomy. Patients were also eligible for inclusion if they met two or more of the following minor criteria: an age of less than 50 years and female sex, a history of recurrent pancreatitis (≥2 episodes), three or more injections of contrast agent into the pancreatic duct with at least one injection to the tail of the pancreas, excessive injection of contrast agent into the pancreatic duct resulting in opacification of pancreatic acini, or the acquisition of a cytologic specimen from the pancreatic duct with the use of

The exclusion criteria are listed in the Supplementary Appendix and were intended to exclude patients in whom ERCP was unsuitable and those who had active pancreatitis, had a contraindication to the use of NSAIDs (e.g., creatinine level, >1.4 mg per deciliter [124 μmol per liter] or active peptic ulcer disease), were already taking NSAIDs (other than cardioprotective aspirin), or had an anticipated low risk of post-ERCP pancreatitis (e.g., those with chronic calcific pancreatitis or a pancreatic-head mass or those undergoing routine biliary-stent exchange).

Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how
	11b	If relevant, description of the similarity of interventions
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses

the procedure and in-hospital care were left to the discretion of the endoscopist and clinical-service staff members, who were unaware of study-group assignments. Serum amylase and lipase were measured in hospitalized patients at least once 24 hours after the procedure and subsequently at clinical discretion.

Studiu clinic randomizat DUBLU ORB!!

reportable adverse events were gastrointestinal bleeding, perforation, infection, renal failure, allergic reaction, myocardial infarction, cerebrovascular accident, and death.

STATISTICAL ANALYSIS

The prophylactic placement of pancreatic stents has been shown to reduce the rate of post-ERCP pancreatitis to 5 to 10% among high-risk patients.[14-16] An internal audit of high-risk ERCPs at participating institutions revealed a post-ERCP rate of pancreatitis of approximately 10%, despite routine prophylactic stent placement in appropriate patients. We estimated that 948 patients (474 per study group) would provide a power of at least 80% to detect a 50% reduction in the incidence of post-ERCP pancreatitis, from 10% in the placebo group to 5% in the indomethacin group, on the basis of Fisher's exact test, with a two-sided significance level of 0.05.

For the analysis of the primary end point, we used a two-tailed Fisher's exact test to analyze the difference in the proportion of patients with post-ERCP pancreatitis in the indomethacin group and the placebo group, with a final two-sided P value of less than 0.041 indicating statistical significance. This P value reflects the partial spending of degrees of freedom of statistical testing that

INTERVENTION

All procedure-related interventions were dictated by the performing endoscopist. Immediately after the procedure, if the endoscopist and research coordinator determined that inclusion criteria had been met, patients were randomly assigned to receive either two 50-mg indomethacin suppositories or two identical-appearing placebo suppositories. The randomization schedule, which was stratified according to study center, was generated centrally at the University of Michigan.

The suppositories were administered immediately after ERCP while the patient was still in the procedure room. The rectal route was selected on the basis of available pilot data suggesting that only rectal NSAIDs are effective in preventing post-ERCP pancreatitis, perhaps owing to more rapid and complete bioavailability than with oral administration.[10,18] The indomethacin suppositories were purchased from two vendors: G&W Laboratories and Custom Med Apothecary. Formal potency testing confirmed that the vendors provided indomethacin suppositories that were pharmacodynamically equivalent (Analytic Research Laboratories).

OUTCOMES

The primary outcome of the study was the development of post-ERCP pancreatitis, which was defined according to consensus criteria[19] (details are provided in the Supplementary Appendix). Briefly, post-ERCP pancreatitis was diagnosed if there was a new onset of pain in the upper abdomen, an elevation in pancreatic enzymes of at least three times the upper limit of the normal range 24 hours after the procedure, and hospitalization for at least 2 nights. The secondary outcome was the development of moderate or severe post-ERCP pancreatitis (see the Supplementary Appendix). Data regarding the length of hospital stay for patients with post-ERCP pancreatitis were collected prospectively, but the duration of hospitalization was not a prespecified outcome measure and was therefore analyzed post hoc.

Results

Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome
	13b	For each group, losses and exclusions after randomisation, together with reasons
Recruitment	14a	Dates defining the periods of recruitment and follow-up
	14b	Why the trial ended or was stopped
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group

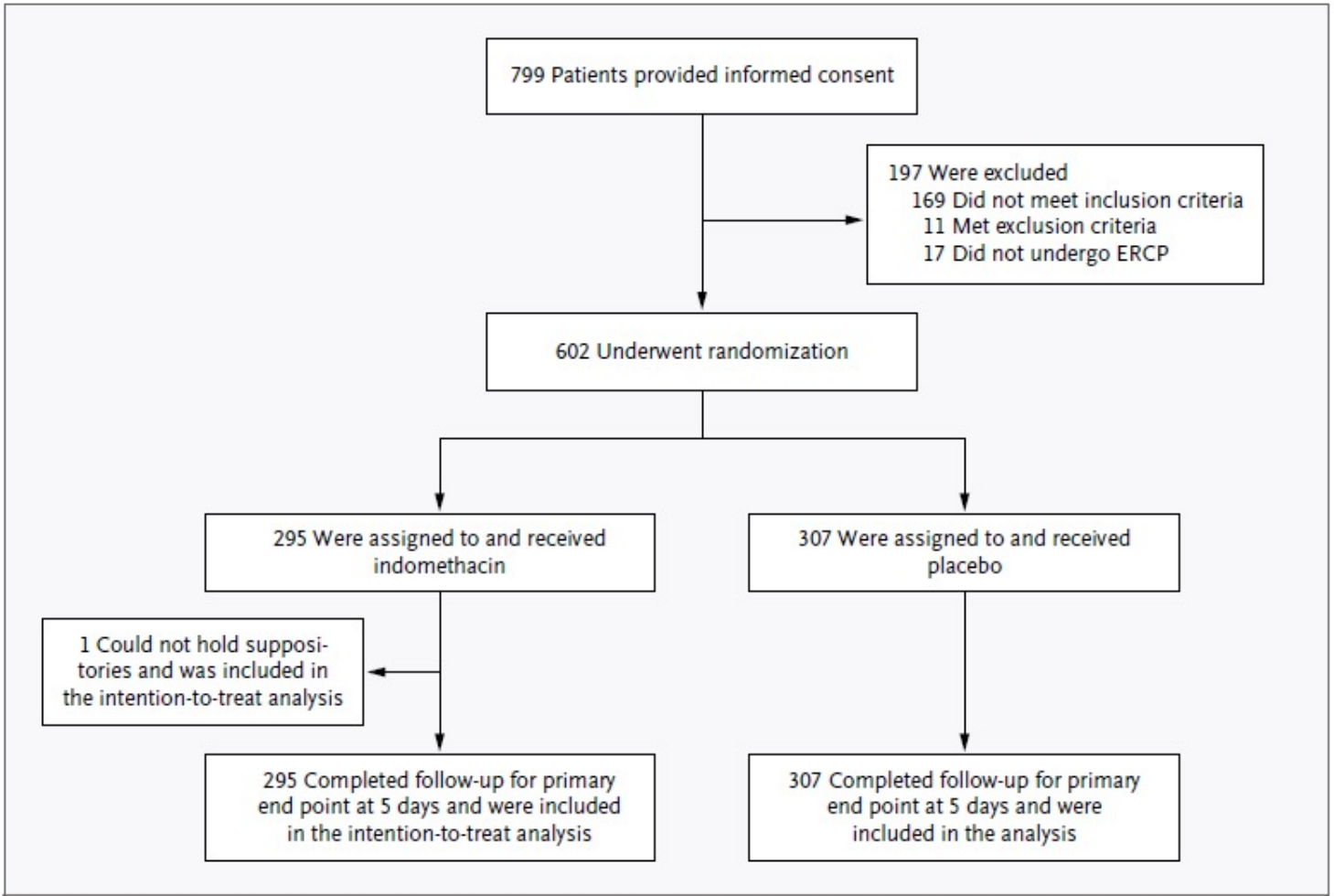


Figure 1. Enrollment and Outcomes.

Table 1. Characteristics of the Patients at Baseline.*

Characteristic	Indomethacin (N=295)	Placebo (N=307)
Age — yr	44.4±13.5	46.0±13.1
Female sex — no. (%)	229 (77.6)	247 (80.5)
Clinical suspicion of sphincter of Oddi dysfunction — no. (%)†		
Any	248 (84.1)	247 (80.5)
Type 1	38 (12.9)	43 (14.0)
Type 2	139 (47.1)	135 (44.0)
Type 3	71 (24.1)	69 (22.5)
Documented on manometry	155 (52.5)	160 (52.1)
History of post-ERCP pancreatitis — no. (%)	47 (15.9)	49 (16.0)
History of recurrent pancreatitis — no. (%)	85 (28.8)	94 (30.6)
Difficult cannulation (>8 attempts) — no. (%)	79 (26.8)	77 (25.1)
Precut sphincterotomy — no. (%)‡	15 (5.1)	17 (5.5)
Pancreatography		
Patients — no. (%)	249 (84.4)	260 (84.7)
Median no. of injections of contrast agent into pancreatic duct	2	2
Therapeutic pancreatic sphincterotomy — no. (%)	172 (58.3)	170 (55.4)
Pancreatic acinarization — no. (%)§	15 (5.1)	12 (3.9)
Therapeutic biliary sphincterotomy — no. (%)	172 (58.3)	171 (55.7)
Ampullectomy — no. (%)	9 (3.1)	9 (2.9)
Placement of pancreatic stent — no. (%)	246 (83.4)	250 (81.4)
Trainee involvement in ERCP — no. (%)	142 (48.1)	140 (45.6)

Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended

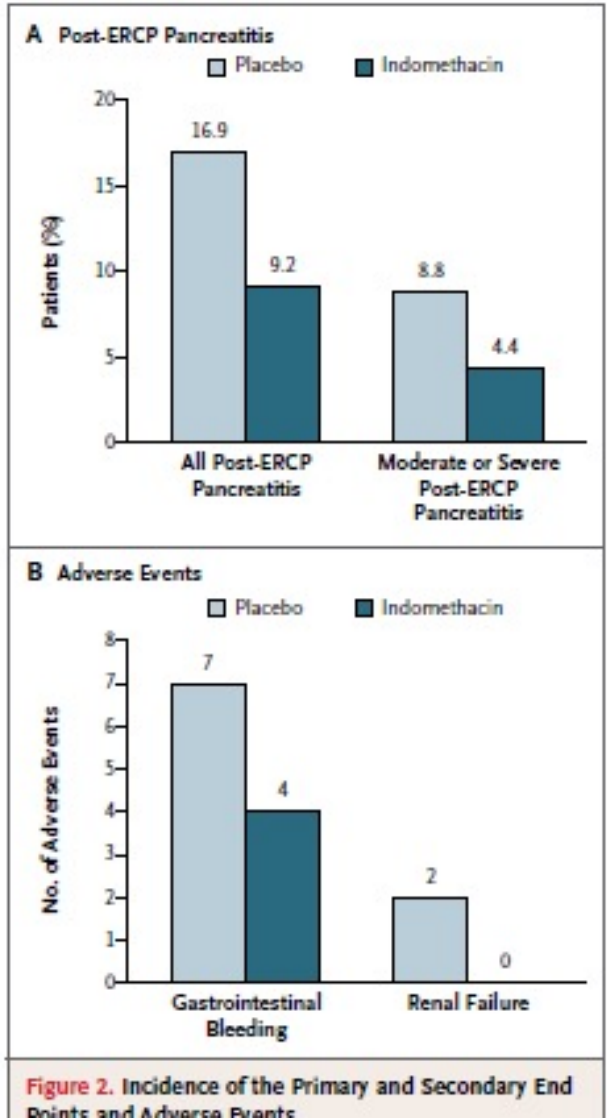
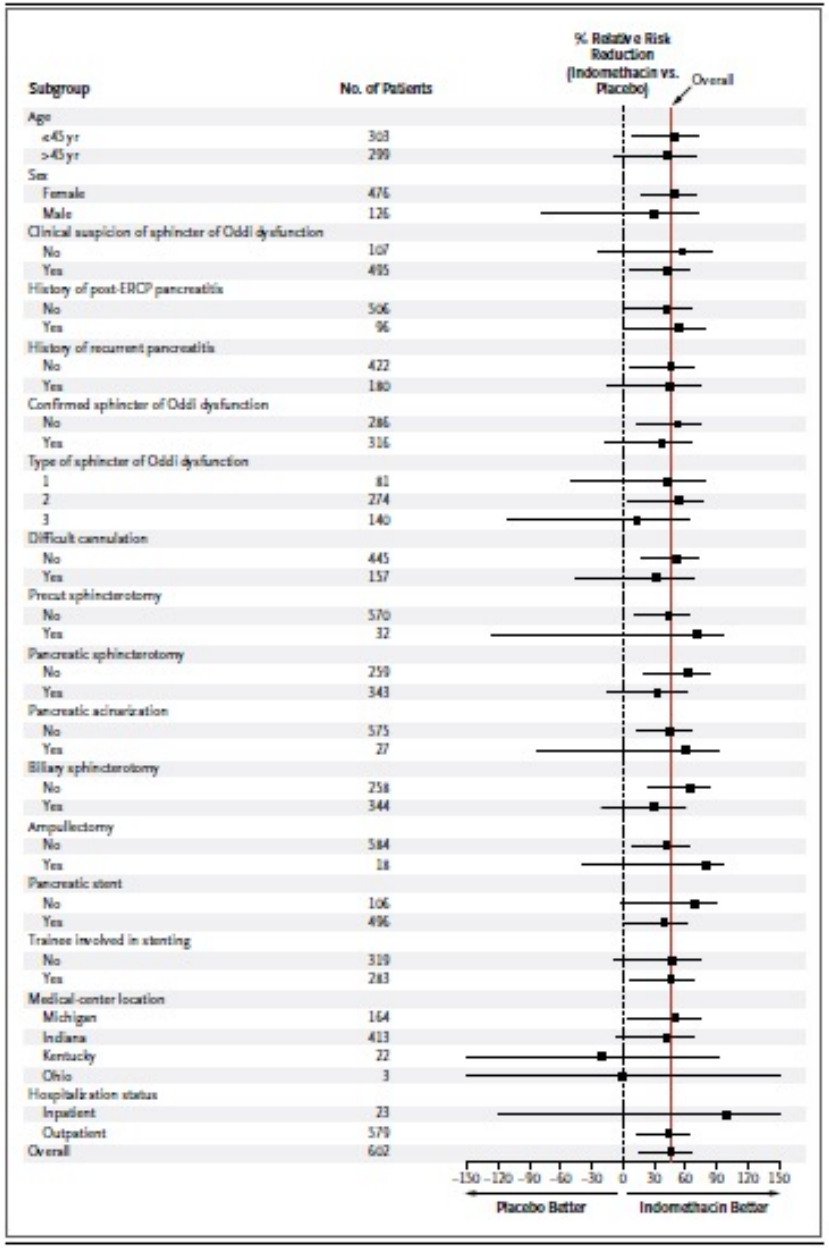


Figure 2. Incidence of the Primary and Secondary End Points and Adverse Events

Marimea efectului terapiei cu indometacin pentru aparitia pancreatita post ERCP?

Marimea efectului terapiei cu indometacin pentru aparitia pancreatitei moderat-severe post ERCP?

Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)



ADVERSE EVENTS

There were 13 adverse events that were potentially attributable to the study intervention (Fig. 2). Clinically significant bleeding occurred in 11 patients (1.8%): 4 in the indomethacin group and 7 in the placebo group (P=0.72). None of the bleeding events resulted in transfusion of more than 2 units of packed red cells or required angiography or surgery for treatment. Two cases of acute renal failure occurred, both in the placebo group. There were no myocardial infarctions, strokes, or deaths at 30-day follow-up.

Discussion		
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses
Generalisability	21	Generalisability (external validity, applicability) of the trial findings
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence

of patients' risk of post-ERCP pancreatitis. Additional studies will be necessary to reproduce our results in different patient populations and to determine whether indomethacin is effective in low-

was 18.8%.[...]

In summary, prophylactic rectal indomethacin significantly reduced the incidence and severity of post-ERCP pancreatitis in patients at elevated risk for this complication, particularly in those with a clinical suspicion of sphincter of Oddi dysfunction.

Congruent with previous clinical trials evaluating NSAIDs in the prevention of post-ERCP pancreatitis, the risk of adverse events that were potentially attributable to indomethacin in this study was similar in the two study groups. Specifically, there was no significant between-group difference in the frequency or severity of bleeding events. This finding is consistent with previously published data suggesting that NSAIDs in standard doses do not increase the risk of bleeding after biliary sphincterotomy.[2,22] Of note, patients with contraindications to NSAIDs, such as renal failure and active peptic-ulcer disease, were excluded from this study.