

SPECIAL SOFTWARE AND TOOLS (IT)

Internet-based data management tool for systematic reviews

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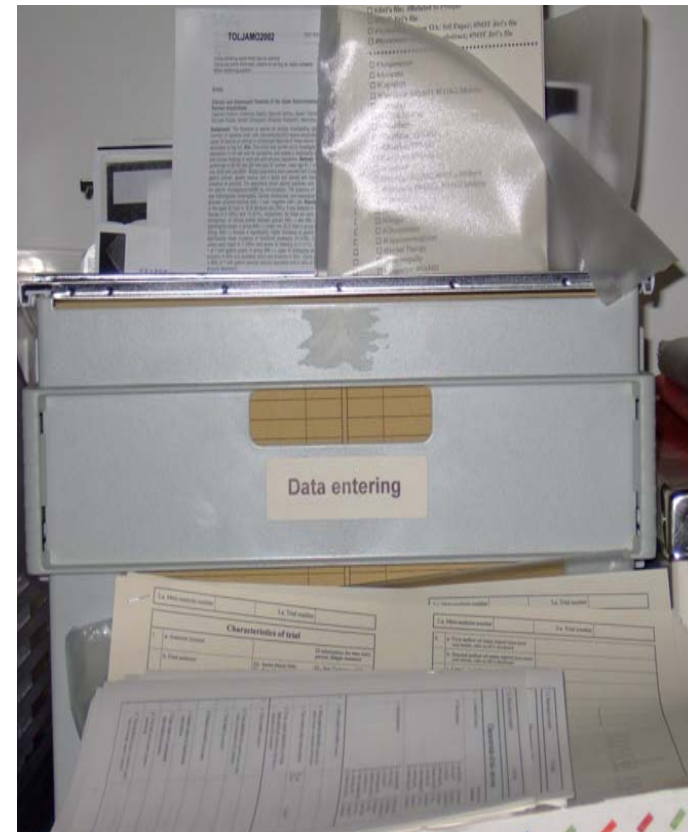
University of Bern, 2mt-software, Nordic Cochrane
Centre

Daily business

> Data extraction

2.a. Meta-analysis number	3.a. Trial number
10. Described as randomised	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no
11. a. Individuals as units of randomisation	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no, explain below <input type="checkbox"/> unclear
b. If not individuals, state unit of randomisation	<input type="checkbox"/> unclear
12. a. Stratified randomisation	<input checked="" type="checkbox"/> yes, explain below <input type="checkbox"/> no <input type="checkbox"/> unclear
b. State criteria used for stratification (if applicable)	Age, sex, <input checked="" type="checkbox"/> * see comment on back
13. a. Description of generation of allocation sequences	<input checked="" type="checkbox"/> randomised table <input type="checkbox"/> computer generated <input type="checkbox"/> minimisation <input type="checkbox"/> coin tossing <input type="checkbox"/> shuffling cards <input type="checkbox"/> drawing lots <input type="checkbox"/> other, describe below <input type="checkbox"/> unclear
b. Describe generation (if not listed above)	
c. Adequate generation of allocation sequences	<input checked="" type="checkbox"/> yes <i>No is correct</i> <input type="checkbox"/> no <input type="checkbox"/> unclear
14. a. Description of concealment of allocation	<input type="checkbox"/> assignment envelopes with allocations in unreadable file, accessible only after provision of patient details <input type="checkbox"/> coded pharmacy (drug packs, independently prepared & coded) <input checked="" type="checkbox"/> other, describe below <input type="checkbox"/> on-site computer system <input type="checkbox"/> unclear
b. Describe concealment of allocation (if not listed above)	<i>random tables site lost touched</i>
c. Adequate concealment of allocation	<input checked="" type="checkbox"/> yes <input type="checkbox"/> unclear
If assignment envelopes were used, these were	
15. a. Sealed	<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unclear
b. Opaque	<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unclear
c. Sequentially numbered	<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unclear
16. a. Trial's maximum treatment duration (specify in randomised measurements, weeks; 1 month=4.3 weeks, round to 1 position)	4 <input type="checkbox"/> unclear
b. Trial's maximum follow-up duration (calculate from baseline, weeks; 1 month=4.3 weeks, round to 1 position)	6.8 <input checked="" type="checkbox"/> unclear <i>uncollected → DOB</i>

> Data storage



Process of performing systematic reviews is complex

- > Several people involved, across countries
- > Large amount of data
 - Administrative data
 - References
 - Fulltext reports
 - Data extraction forms
 - Extraction data
 - Error-prone process
- > Database systems potential to help reviewers

- To develop a web-based data management system for systematic reviews that is flexible and able to assist in all steps of the review process which is for free for Cochrane users

Technical details

- > Based on personalized web information management system used for clinical trials, studies, registries (WebSpirit®)
- > Implemented in PHP
- > Internet connection SSL encrypted
- > Relational database (PostgreSQL)
- > Linux server

Process of performing a systematic review

1.	Defining a systematic review (set-up)	Archie, RevBase
2.	Searching reports in external resources	e.g. CENTRAL
3.	Importing reports/references into a systematic review	RevBase
4.	Scanning for duplicates of reports	RevBase
5.	Screening of reports (Title/abstract evaluation)	RevBase
6.	Consensus on screening	RevBase
7.	Eligibility of reports (Fulltext evaluation)	RevBase
8.	Consensus on eligibility	RevBase
9.	Assigning reports to studies and eligibility of studies	RevBase
10.	Consensus on study assignment	RevBase
11.	Extracting data from studies	RevBase
12.	Consensus on extracted data	RevBase
13.	Exporting data e.g. into RevMan	RevBase
14.	Narrative Synthesis	RevMan
15.	Statistical Synthesis	RevMan



REVBASE

[Imprint](#)[Login](#)

Please enter your username and your password:

Username: Password:

UNIVERSITÄT
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Defining PICOTs

Comparators



Review: Chondroitin for patients with osteoarthritis of the knee or hip

group: bern
user: trelle

[review] Definition of Comparators

Comparators

	Name		Description		MeSH	
1.	<input type="text" value="Chondroitin"/>		<input type="text" value="Chondroitin and standard care"/>		<input type="text" value="Chondroitin Sulfates"/>	
2.	<input type="text" value="Acetaminophen"/>		<input type="text" value="Acetaminophen and standard care"/>		<input type="text" value="Acetaminophen"/>	
3.	<input type="text" value="Placebo"/>		<input type="text" value="Placebo and standard care"/>		<input type="text" value="Control groups"/>	
4.	<input type="text"/>		<input type="text"/>		<input type="text"/>	

Submit

- ▼ Definition
 - User Roles
- PICOTs
 - Comparators**
 - Comparisons
 - Groups
 - Outcomes
 - Timepoints
- + Data Extraction Forms
- Import Reports
- Duplicate Scan
- ▶ Screen Reports
- ▶ Include Reports
- ▶ Include Studies
- ▶ Extract Data
- Export Data
- Exit Review

- Imprint

- ▶ User Settings
- Logout

Screening reports (title/abstract)



Review: Chondroitin for patients with osteoarthritis of the knee or hip

 group: bern
 user: trelle

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[Uebelhart2004] Screening of Report

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Screening	
Screening state:	<input checked="" type="radio"/> potentially relevant <input type="radio"/> not relevant <input type="radio"/> not relevant, but interesting
✎ 📄	
Report	
Authors:	Uebelhart D, Malaise M, Marcolongo R, et al.
✎ 📄	
Title:	Intermittent treatment of knee osteoarthritis with oral chondroitin sulfate: a one-year, randomized, double-blind, multicenter study versus placebo
✎ 📄	
Abstract:	<p>OBJECTIVE: To investigate the efficacy and tolerability of a 3-month duration, twice a-year, intermittent treatment with oral chondroitin sulfate (CS) in knee osteoarthritis (OA) patients.</p> <p>DESIGN: A total of 120 patients with symptomatic knee OA were randomized into two groups receiving either 800mg CS or placebo (PBO) per day for two periods of 3 months during 1 year. Primary efficacy outcome was Lequesne's algo-functional index (AFI); secondary outcome parameters included VAS, walking time, global judgment, and paracetamol consumption. Radiological progression was assessed by automatic measurement of medial femoro-tibial</p>
✎ 📄	
Keywords:	Acetaminophen/therapeutic use, Administration, Oral, Analgesics, Non-Narcotic/therapeutic use, Chondroitin Sulfates/* administration & dosage/adverse effects, Delayed-Action Preparations/* administration &
✎ 📄	
Journal:	Osteoarthritis Cartilage
✎ 📄	
Year:	2004
✎ 📄	
Publication type:	Clinical Trial, Journal Article, Multicenter Study, Randomized
✎ 📄	

Next Report

File upload



- Definition
- Import Reports
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 - Uebelhart2004
- Include Reports
 - Clegg2006 - Upload
 - Clegg2006 - Full Text Eval.
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[Clegg2006] Eligibility of Report - Full Text Upload

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Eligibility

Eligibility state: relevant not relevant unclear



Full Report

Upload report: [View file](#)



Short Report

Authors: Clegg DO, Reda DJ, Harris CL, Klein MA, O'Dell JR, Hooper MM, Bradley JD, Bingham CO 3rd, Weisman MH, Jackson CG, Lane NE, Cush JJ, Moreland LW, Schumacher HR Jr, Oddis CV, Wolfe F, Molitor JA, Yocum DE, Schnitzer TJ, Furst



Title: Glucosamine, chondroitin sulfate, and the two in combination for painful knee osteoarthritis



Abstract: Background
Glucosamine and chondroitin sulfate are used to treat osteoarthritis. The multicenter, double-blind, placebo- and celecoxib-controlled Glucosamine/chondroitin Arthritis Intervention Trial (GAIT) evaluated their efficacy and safety as a treatment for knee pain from osteoarthritis.
Methods We randomly assigned 1583 patients with symptomatic knee osteoarthritis to receive 1500 mg of glucosamine daily, 1200 mg of chondroitin



Keywords:



Journal: N Engl J Med



Year: 2006



Publication type:



Consensus on including reports



Review: Chondroitin for patients with osteoarthritis of the knee or hip

 group: bern
 user: trelle

Eligibility of Reports - Consensus

 Consensus State: 25 of 18 reports are consented, -7 to be done.

Report ID	Authors	Title	Peter Jüni	Sven Trelle	Consensus
Alekseeva1999	Alekseeva LI, Benevolenskaia LI, Nasonov EL, Chich...	Structum (chondroitin sulfate)--a new agent for the treatment of osteoarthritis	relevant	relevant	relevant
Alekseeva2005	Alekseeva LI, Chichasova NV, Benevolenskaia LI, Na...	Combined medication ARTRA in the treatment of osteoarthritis	relevant	relevant	relevant
Bourgeois1998	Bourgeois P, Chales G, Dehais J, Delcambre B, Kunt...	Efficacy and tolerability of chondroitin sulfate 1200 mg/day vs chondroitin sulfate 3 x 400 mg/day vs placebo.	relevant	relevant	relevant
Bruyere2007	Bruyere O, Reginster JY.	Glucosamine and chondroitin sulfate as therapeutic agents for knee and hip osteoarthritis.	relevant	relevant	relevant
Conrozier1998	Conrozier T.	Anti-arthritis treatments: efficacy and tolerance of chondroitin sulfates (CS 4&6)	relevant	relevant	relevant
Hochberg2008	Hochberg MC, Clegg DO	Potential effects of chondroitin sulfate on joint swelling: a GAIT report	not relevant	not relevant	not relevant
Kirkley2008	Kirkley A, Birmingham TB, Litchfield RB, et al	A randomized trial of arthroscopic surgery for osteoarthritis of the knee	relevant	relevant	relevant
Messier2007	Messier SP, Mihalko S, Loeser RF, et al	Glucosamine/chondroitin combined with exercise for the treatment of knee osteoarthritis: a preliminary study	relevant	relevant	relevant
Michel2005	Michel BA, Stucki G, Frey D, et al	Chondroitins 4 and 6 sulfate in osteoarthritis of the knee: a randomized, controlled trial.	relevant	unclear	----
Moreau2003	Moreau M, Dupuis J, Bonneau NH, Desnoyers M.	Clinical evaluation of a nutraceutical, carprofen and meloxicam for the treatment of dogs with osteoarthritis.	relevant	unclear	----
Morelli2003	Morelli V, Naquin C, Weaver V.	Alternative therapies for traditional disease states: osteoarthritis.	relevant	relevant	relevant
Morreale1996	Morreale P, Manopulo R, Galati M, Boccanera L, Sap...	Comparison of the antiinflammatory efficacy of chondroitin sulfate and diclofenac sodium in patients with knee osteoarthritis.	relevant	unclear	----
Sawitzke2008	Sawitzke AD, Shi H, Finco MF, Dunlop DD, Bingham C...	The effect of glucosamine and/or chondroitin sulfate on the progression of knee osteoarthritis: A report from the glucosamine/chondroitin arthritis intervention trial	not relevant	relevant	----
Uebelhart1998	Uebelhart D, Thonar EJ, Delmas PD, Chantraine A, V...	Effects of oral chondroitin sulfate on the progression of knee osteoarthritis: a pilot study.	relevant	relevant	relevant
Uebelhart2004	Uebelhart D, Malaise M, Macrolongo P, et al	Intermittent treatment of knee osteoarthritis with oral chondroitin sulfate: a one-year, randomized, double-blind, multicenter study.	relevant	relevant	relevant



- Definition
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List of included studies



Review: Chondroitin for patients with osteoarthritis of the knee or hip

group: bern
user: trelle

- Definition
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Eligibility State:


3 of 8 studies are included, 1 studies excluded, 2 to be done.

included
 excluded
 awaiting assessment
 ongoing

Study ID	#Reports	Assigned Reports	Inclusion
Artra1998	3	Alekseeva1999 Alekseeva2005 <u>Conromier1998</u>	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/>
Bourgeois1998	1	Bourgeois1998	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/>
Clegg2006	3	Sawitzke2008 Hochberg2008 Clegg2006	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/>
Kirkley2008	3	Bruyere2007 Kirkley2008 Messier2007	<input type="checkbox"/> <input checked="" type="checkbox"/>
Michel2005	2	Uebelhart2004 Michel2005	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/>
Moreau2003	1	Moreau2003	<input type="checkbox"/> <input checked="" type="checkbox"/>
Morelli2003	1	Morelli2003	<input checked="" type="checkbox"/>
Morreale1996	1	Morreale1996	<input checked="" type="checkbox"/>

Creating data extraction forms





REVBASE

Review: Chondroitin for patients with osteoarthritis of the knee or hip

group: bern
user: trelle

[review] Study Level Extraction Template Form edit

- Definition
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 - Comparisons
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- Data Extraction Forms
 - Study Level**
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Minimal Data Set

Randomization list:

Generation of randomization list:	<input style="width: 90%;" type="text" value="----"/>	<input style="width: 20px; height: 20px;" type="button" value="v"/>	<input style="width: 15px; height: 15px;" type="button" value="✎"/> <input style="width: 15px; height: 15px;" type="button" value="📄"/>
Description of generation of randomization list:	<input style="width: 95%; height: 40px;" type="text"/>		
Comment:	<input style="width: 95%; height: 40px;" type="text"/>		
Adequate generation of randomization list:	<input type="radio"/> yes <input type="radio"/> no		

Concealment of allocation:

Concealment of allocation:	<input style="width: 90%;" type="text" value="----"/>	<input style="width: 20px; height: 20px;" type="button" value="v"/>	<input style="width: 15px; height: 15px;" type="button" value="✎"/> <input style="width: 15px; height: 15px;" type="button" value="📄"/>
Description of concealment of allocation:	<input style="width: 95%; height: 40px;" type="text"/>		
Comment:	<input style="width: 95%; height: 40px;" type="text"/>		
Adequate concealment:	<input type="radio"/> yes <input type="radio"/> no		

Creating data extraction forms

- Definition
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[review] Study Level Extraction Template Form

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Minimal Data Set

Randomization list:

Generation of randomization list:



Description of generation of randomization list:



Comment:



Adequate generation of randomization list: yes no



Concealment of allocation:

Concealment of allocation:



Description of concealment of allocation:



Comment:



Adequate concealment: yes no



Additional Fields 145

Study: 145

Study settings:

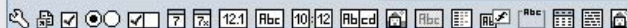
- Tertiary care 1
- Secondary care 2
- Primary care 3
- Other 4

studysset



Description of study setting:

studyssetdesc



Study centers: 161

Number:

centers



Creating a data extraction field

Plausibility checks of field *Study settings*

User Defined Checks		Form Checks	Help
no.	type	condition	
1.	error <input type="button" value="v"/>	<input type="text"/>	
	on true	<input type="text"/>	
	on false	<input type="text"/>	
2.	error <input type="button" value="v"/>	<input type="text"/>	
	on true	<input type="text"/>	
	on false	<input type="text"/>	

Plausibility shortcuts:

[set mandatory] [set bool dependency] [show/hide group] Parameter:

Codebook/data extraction guidelines

The screenshot shows the REVBASE web application interface. At the top, the title is "Review: Chondroitin for patients with osteoarthritis of the knee or hip" and the user information is "group: bern user: trelle". The left sidebar contains a navigation menu with categories like "Definition", "Data Extraction Forms", and "User Settings". The main content area is titled "[review] Study Level Extraction Template Form" and is divided into sections for "Minimal Data Set" and "Additional Fields".

Minimal Data Set

Randomization list:

- Generation of randomization list: [dropdown menu]
- Description of generation of randomization list: [text area]
- Comment: [text area]
- Adequate generation of randomization list: [checkbox]

Concealment of allocation:

- Concealment of allocation: [checkbox]
- Description of concealment of allocation: [text area]
- Comment: [text area]
- Adequate concealment of allocation: yes no

Additional Fields

Study: 145

Study settings:

- Tertiary care 1
- Secondary care 2
- Primary care 3
- Other 4

A yellow callout box titled "Adequate methods include" is overlaid on the "Adequate generation of randomization list" field. It contains the following text:

Adequate methods include

- Central randomization: The central randomization office was remote from patient recruitment centres. Participant details were provided, for example, by phone, fax or email and the allocation sequence was concealed to individuals staffing the randomization office until a participant was irreversibly registered.
- Sequentially numbered drug containers: Drug containers prepared by an independent pharmacy were sequentially numbered and opened sequentially. Containers were of identical appearance, tamper-proof and equal in weight.
- Sequentially numbered, opaque, sealed envelopes: Envelopes were sequentially numbered and opened sequentially only after participant details were written on the envelope. Pressure sensitive or carbon paper inside the envelope transferred the participant's details to the assignment card. Cardboard or aluminium foil inside the envelope rendered the envelope impermeable to intense light. Envelopes were sealed using tamper proof security tape.

For more information see chapter 8.10.2 of the Cochrane Handbook for Systematic Reviews of Interventions (<http://www.cochrane-handbook.org/>)

Study characteristics extraction



Review: Chondroitin for patients with osteoarthritis of the knee or hip

group: bern
user: trelle

edit

[Michel2005] Study Level Extraction

Assigned Reports: Clegg2006 Michel2005 Hochberg2008

Minimal Data Set

Randomization list:

Generation of randomization list:

Computer generated

Description of generation of randomization list:

The randomization was done by computer in blocks of 4

Comment:

Adequate generation of randomization list:

yes no

Concealment of allocation:

Concealment of allocation:

Description of concealment of allocation:

Comment:

No details provided

Adequate concealment:

yes no

Additional Fields

Study:

Study settings:

Tertiary care
 Secondary care
 Primary care
 Other

Outcome extraction



Review: Chondroitin for patients with osteoarthritis of the knee or hip

group: bern
user: trelle

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 - Michel2005
 - Michel2005 - Response to T...
- Export Data
- Exit Review
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[Michel2005] Binary Outcome: Response to Treatment

Binary Outcome: Response to Treatment

Numbers:

	Comparator 1: Chondroitin and standard care	Comparator 2: Standard care
Total number of patients randomized	60	59
Patient	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Patient-years	<input type="checkbox"/>	<input type="checkbox"/>
Number of patients analyzed	60	59
Number of patients-years analyzed		
All randomized patients analyzed:	<input checked="" type="radio"/> yes <input type="radio"/> no <input type="radio"/> unclear	
All randomized patients analyzed in the group they were randomized:	<input type="radio"/> yes <input type="radio"/> no <input type="radio"/> unclear	

Events:

	Comparator 1: Chondroitin and standard care	Comparator 2: Standard care
Number of patients with event		
Proportion of patients with event		

Risk:

Relative Risk:	
Rate ratio:	

Data transfer

Review Manager 5

File Edit Format View Tools Table Window Help

Regular treatment with formoterol for chronic asthma: serious adverse events

Text of Review

Title
 Review information
 Main text
 Tables
 Characteristics of studies
 Characteristics of included
 Bensch 2001
 Risk of bias table
 Bensch 2002
 Busse 2004
 Corren 2007
 Ekstrom 1998
 Ekstrom 1998a
 FitzGerald 1999
 Hekking 1990
 Kesten 1991
 Kozlik-Feldmann 1996
 LaForce 2005
 Levy 2005
 Molimard 2001
 Noonan 2006
 Pleskow 2003
 SD-037-0344

Risk of bias table

Item	Judgement	Description
Adequate sequence generation?	Unclear	Not reported
Allocation concealment?	Unclear	Not reported
Blinding?	Yes	Double-blind, double dummy. Matching capsules and devices
Incomplete outcome data addressed?	Unclear	All patients included in the safety analysis
Free of selective reporting?	Yes	No SAE data in paper publication, but FDA submission provided SAE information

Bensch 2002

Methods	A randomized, double-blind, placebo-controlled, multinational, multicenter, pediatric study over 52 weeks at 42 centers. Initial run-in period of 2 weeks.
Participants	Population: 518 children, (5-12) years with persistent asthma on

Outlook

- > Potential for integration with Archie
- > Import reports in other formats than RIS
- > Offline use (via XML-upload)