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Amitriptyline to relieve pain in juvenile idiopathic arthritis: a pilot study using Bayesian meta-analysis of multiple N-of-1 clinical trials

Submission date
29/05/2006

Recruitment status
No longer recruiting

Registration date
14/07/2006

Overall study status
Completed

Last Edited
01/10/2008

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
77986

Study information

Scientific Title

Study objectives
1. Serial N-of-1 trials analyzed using Bayesian methods can be used to estimate population effects of interventions
2. Amitriptyline will reduce pain in children with polyarticular course juvenile idiopathic arthritis, as compared to placebo

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Board at Sick Kids Hospital in Toronto, as well as the Research Ethics Board at the IWK Health Centre in Halifax, Nova Scotia both approved this study in September 1999

Study design
Randomized, placebo-controlled, double-blind, multiple crossover design

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Juvenile idiopathic arthritis

Interventions
Amitriptyline 25 mg every hour of sleep (qhs) for two weeks per treatment period versus placebo

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Amitriptyline

Primary outcome(s)
Pain (measured with 6-10 cm visual analogue scale [VAS] over two days)

Key secondary outcome(s))
1. Sleep
2. Stiffness
3. Physical function
4. Active and swollen joint counts
5. Fatigue

Completion date
01/01/2002

Eligibility

Key inclusion criteria
1. Aged 10-18 years of age
2. Polyarticular course juvenile idiopathic arthritis
3. At least one active joint
4. Minimum pain score of 1 cm

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
10 years

Upper age limit
18 years

Sex
All

Key exclusion criteria
Prolonged QT interval

Date of first enrolment
01/10/1999

Date of final enrolment
01/01/2002

Locations

Countries of recruitment
Canada

Study participating centre
IWK Health Centre
Halifax
Canada
B3K 6R8

Sponsor information

Organisation
IWK Health Centre (Canada)

ROR
https://ror.org/0064zg438

Funder(s)

Funder type
Research organisation

Funder Name
The Canadian Institutes of Health Research (Canada) (ref: 77986) - the funding for this trial predates the transition of the major public funding body in Canada from the Medical Research Council to the Canadian Institutes of Health Research.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2007		Yes	No