

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

☐ Prospectively registered

☐ Protocol

Registration date
14/07/2006

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
01/10/2008

Condition category
Musculoskeletal Diseases

☐ 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

1. Sleep
2. Stiffness
3. Physical function
4. Active and swollen joint counts
5. Fatigue

Overall study start date

01/10/1999

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

Age group

Child

Lower age limit

10 Years

Upper age limit

18 Years

Sex

Both

Target number of participants

8

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)

Sponsor details

5850 University Avenue

Halifax

Canada

B3K 6R8

Sponsor type

Hospital/treatment centre

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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