ISRCTN81030001 https://doi.org/10.1186/ISRCTN81030001

Double blind, placebo controlled crossover study of the efficacy and side effects of low dose amitriptyline treatment for chronic pain, disordered sleep and reduced mobility in children with Epidermolysis Bullosa

Submission date
18/06/2010

Recruitment status
No longer recruiting

Registration date
18/06/2010

Overall study status
Completed

Last Edited
10/08/2016

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

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
3217

Study information

Scientific Title
Double blind, placebo controlled crossover study of the efficacy and side effects of low dose amitriptyline treatment for chronic pain, disordered sleep and reduced mobility in children with Epidermolysis Bullosa

Acronym
Amitriptyline in EB Pain

Study objectives
In this study we propose to investigate the analgesic efficacy of low dose oral amitriptyline in a randomised, double blind, crossover design trial in children 8 - 18 years with Epidermolysis Bullosa (EB), a painful hereditary skin condition.

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC approved (ref: 06/Q0508/3)

Study design
Single centre randomised interventional treatment trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Medicines for Children Research Network; Subtopic: All Diagnoses; Disease: All Diseases

Interventions
Child Activity Limitation Interview (CALI):
In addition to classical pain measurement, using the Visual Analogue Scales (VAS), quality of life will be measured using a simple, recently developed questionnaire tool (the CALI) which defines impairments in patient selected developmentally appropriate activities.

Mobility:
Mobility will be assessed by a physiotherapist, with particular emphasis on quantifiable parameters of walking gait including use of the GAITERITE commercial measurement system.

Side effects:
Side effects will be monitored, cardiovascular effects will be investigated using ECG (electrocardiograph) and echocardiography.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome(s)
Self assessment of pain using a linear VAS

Key secondary outcome(s))
1. Quantitative assessment of mobility, measured by a physiotherapist
2. Reporting of sleep pattern and nocturnal pain

Completion date
12/02/2010

Eligibility

Key inclusion criteria
1. Children age 6 - 18 years
2. EB and pain
3. Not responding to conventional analgesia
4. Undergoing ongoing care at Great Ormond Street Hospital

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 years

Upper age limit
18 years

Sex
Not Specified

Key exclusion criteria
1. Amitriptyline therapy in previous 6 weeks
2. Contra-indication to tricyclic antidepressants

Date of first enrolment
26/09/2006

Date of final enrolment

12/02/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Somers Clinical Research Facility
London
United Kingdom
WC1N 3JH

Sponsor information

Organisation
University College London (UCL) Institute of Child Health (UK)

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Research organisation

Funder Name
Dystrophic Epidermolysis Bullosa Research Association (DEBRA) (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration