

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	☐ Prospectively registered
		☐ Protocol
Registration date 18/06/2010	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 10/08/2016	Condition category Skin and Connective Tissue Diseases	☐ 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)

Primary study design

Interventional

Study design

Single centre randomised interventional treatment trial

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