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	 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 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

Secondary study design Randomised controlled trial

Study setting(s) Hospital

Study type(s) Treatment

Participant information sheet

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 measure Self assessment of pain using a linear VAS

Secondary outcome measures

- 1. Quantitative assessment of mobility, measured by a physiotherapist
- 2. Reporting of sleep pattern and nocturnal pain

Overall study start date

26/09/2006

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

Age group Child

Lower age limit

6 Years

Upper age limit 18 Years

Sex Not Specified

Target number of participants Planned sample size: 40; UK sample size: 40

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 England

United Kingdom

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)

Sponsor details 30 Guilford Street London England United Kingdom WC1N 1EH **Sponsor type** University/education

Website http://www.ich.ucl.ac.uk/

ROR https://ror.org/02jx3x895

Funder(s)

Funder type Research organisation

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

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