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# 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

**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
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**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