

# Sleep disturbance and learning in children with Benign Epilepsy of Childhood with Centrotemporal Spikes (BECCTS)

<b>Submission date</b> 11/05/2011	<b>Recruitment status</b> Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 13/07/2011	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 24/02/2020	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Benign epilepsy of childhood with centrotemporal spikes (BECCTS), also known as Benign Rolandic epilepsy, is one of the most common types of epilepsy in children. Unlike many other forms of epilepsy, BECCTS only affects children and the associated seizures usually disappear by the time the child is 16 years old. In most cases these seizures only happen when the child is asleep and do not last for very long. It has been found that sleep and drowsiness causes a surge of electrical activity in the centrotemporal region of the brain (centrotemporal spike). This form of epilepsy was previously considered to be harmless (benign) because it was thought to have no long-term ill-effects. However recent studies have shown that children who suffer from BECCTS may have mild learning difficulties. The exact cause of this is not known, as it could be due to the abnormal electrical activity in the brain or because of general interference with sleep. Sulthiame is an anticonvulsant drug which could be used to prevent these centrotemporal spikes, and helping to prevent sleep disturbances. The aim of this study is to find out if treatment with sulthiame could help to improve quality of sleep and help children to improve their learning skills.

### Who can participate?

Children between the ages of 6 and 16 who have been diagnosed with BECCTS within the last 6 months.

### What does the study involve?

Participants are randomly allocated into two groups, who each receive the treatments in a different order. Participants either take sulthiame for six weeks and then the placebo (dummy pill) for six weeks, or take the placebo for six weeks and then six weeks taking sulthiame. The correct dose of sulthiame is calculated for every child using their body weight. Between the sulthiame and placebo treatments, participants have a period of two weeks taking no medication (wash-out period). Before and after each of the treatments, children have their brain waves monitored during sleep and are given a number of tests to find out if their learning has improved.

What are the possible benefits and risks of participating?  
Not provided at time of registration.

Where is the study run from?  
Bristol Royal Hospital for Children (UK)

When is the study starting and how long is it expected to run for?  
September 2011 to August 2013

Who is funding the study?  
1. Epilepsy Research UK (UK)  
2. Waterloo Foundation (UK)

Who is the main contact?  
Dr Finbar O'Callaghan  
finbar.ocallaghan@bristol.ac.uk

## Contact information

Type(s)  
Scientific

Contact name  
Dr Finbar O'Callaghan

Contact details  
Level 6 Education Centre  
Upper Maudlin Street  
Bristol  
United Kingdom  
BS2 8AE  
+44 (0)117 342 0202  
finbar.ocallaghan@bristol.ac.uk

## Additional identifiers

EudraCT/CTIS number  
2011-001571-39

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers  
1260

## Study information

Scientific Title

Investigating the relationship between sleep disturbance and learning in children with Benign Epilepsy of Childhood with Centrotemporal Spikes (BECCTS): a randomised double blind placebo controlled crossover trial

## **Acronym**

BECCTS

## **Study objectives**

1. There will be an association between indices of sleep quality and strength of nocturnal versus daytime Consolidation of Learning in children with untreated BECCTS
2. Treatment of BECCTS will lead to the following changes relative to placebo:
  - 2.1. Abolition of Interictal Epileptic Discharges (IEDs) during slow wave sleep (SWS)
  - 2.2. Improved sleep quality [increased efficiency, reduced number of awakenings, density of sleep spindles and percentage rapid eye movement (REM) and percentage SWS]
  - 2.3. Improved Consolidation of Learning (CoL)

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

South West Research Ethics Committee (Central Bristol), 31/10/21011, ref: 11/SW/0136

## **Study design**

Randomised double blind placebo controlled crossover trial

## **Primary study design**

Interventional

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Hospital

## **Study type(s)**

Treatment

## **Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

## **Health condition(s) or problem(s) studied**

Benign Epilepsy of Childhood with Centrotemporal Spikes (BECCTS), also known as Benign Rolandic Epilepsy

## **Interventions**

1. Sulthiame versus placebo
2. Dose: 5 mg/kg/day

3. Administration: oral capsules, given at approximately 8 hour intervals
4. Duration: (Period A) 6 weeks of sulthiame or placebo, followed by a 2-week wash-out period, followed by (Period B) 6 weeks on the alternate treatment

**Intervention Type**

Drug

**Phase**

Not Applicable

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

Sulthiame

**Primary outcome measure**

1. Frequency of Interictal Epileptic Discharges (IEDs) during slow wave sleep (SWS) on active treatment, relative to placebo, as measured by EEG at baseline, the end of treatment period A and the end of treatment period B
2. Sleep quality [efficiency, number of awakenings, density of sleep spindles and percentage rapid eye movement (REM) and percentage SWS on polysomnography] on active treatment relative to placebo, as measured at baseline, the end of treatment period A and the end of treatment period B
3. Performance on Consolidation of Learning (CoL) tasks on active treatment, relative to placebo, as measured (by validated CoL tools) at baseline, the end of treatment period A and at the end of treatment period B
4. Performance on cognitive assessments including IQ and event related potential (ERP) utilising the commonly employed auditory oddball paradigm as a measure of basic sensory processing and attention, as measured at baseline, the end of treatment period A and the end of treatment period B

**Secondary outcome measures**

No secondary outcome measures

**Overall study start date**

01/09/2011

**Completion date**

31/08/2013

**Reason abandoned (if study stopped)**

Lack of funding/sponsorship

**Eligibility****Key inclusion criteria**

1. Male and female children 6-16 years of age
2. Within 6 months of diagnosis with BECCTS and the onset of symptoms
3. With clinical electroencephalography (EEG) characteristic consistent with typical BECCTS
4. With no current or prior treatment for BECCTS
5. Signed informed (parental) consent

**Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

6 Years

**Upper age limit**

16 Years

**Sex**

Both

**Target number of participants**

20

**Total final enrolment**

2

**Key exclusion criteria**

1. Inability to comply with assessments
2. Any serious intercurrent illness or uncontrolled disease which could compromise participation in the study
3. With contraindications for treatment with sulthiame:
  - 3.1. History of hypersensitivity to sulphonamides
  - 3.2. History of acute porphyria
  - 3.3. History of hyperthyroidism
  - 3.4. History of arterial hypertension
  - 3.5. Impaired renal function
  - 3.6. Psychiatric disorder
  - 3.7. Hereditary galactose intolerance, Lapp lactase deficiency, glucose-galactose malabsorption syndrome

**Date of first enrolment**

01/09/2011

**Date of final enrolment**

31/08/2013

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Level 6 Education Centre**  
Bristol  
United Kingdom  
BS2 8AE

## **Sponsor information**

### **Organisation**

University of Bristol (UK)

### **Sponsor details**

Research & Enterprise Development  
3rd Floor  
Senate House  
Tyndall Avenue  
Bristol  
England  
United Kingdom  
BS8 1TH

### **Sponsor type**

University/education

### **Website**

<http://www.bristol.ac.uk/red/>

### **ROR**

<https://ror.org/0524sp257>

## **Funder(s)**

### **Funder type**

Charity

### **Funder Name**

Epilepsy Research UK (UK)

### **Alternative Name(s)**

ERUK

### **Funding Body Type**

Private sector organisation

### **Funding Body Subtype**

Other non-profit organizations

**Location**

United Kingdom

**Funder Name**

Waterloo Foundation (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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No