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

Submission date
11/05/2011

Recruitment status
Stopped

Registration date
13/07/2011

Overall study status
Stopped

Last Edited
24/02/2020

Condition category
Nervous System Diseases

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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?
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Contact information

Type(s)
Scientific

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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 616 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
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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?
HRA research summary			28/06/2023	No	No