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A randomised double-blind placebo-controlled trial of Fosphenytoin for prevention of seizures in children with acute non-traumatic encephalopathies

Submission date 11/01/2005	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 22/07/2005	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 06/02/2015	**Condition category** Signs and Symptoms	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Charles Newton

Contact details
Neurosciences Unit
Mecklenburgh Square
University College London
London
United Kingdom
WC1N 2AP
+44 (0)20 7837 7618
cnewton@ich.ucl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
SSC 819

Study information

Scientific Title
A randomised double-blind placebo-controlled trial of Fosphenytoin for prevention of seizures in children with acute non-traumatic encephalopathies

Acronym
FOSCOM - FOSphenytoin in non-traumatic COMa

Study objectives
Seizures in acute encephalopathies are associated with neuro-cognitive impairment following recovery. Prevention of the seizures (which may manifest as convulsions, abnormal motor posturing or electrographic seizures) during the acute illness may improve the neuro-cognitive outcome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Acute non-traumatic encephalopathies

Interventions
This is a double blind randomised controlled trial to evaluate the safety and efficacy of a single intramuscular (im) injection of Fosphenytoin, 20 mg Phenytoin equivalents/kg in children with acute non-traumatic encephalopathies, given at admission to prevent seizures and abnormal motor posturing during stay in hospital and neuro-cognitive deficits assessed at three and 24 months. The control intervention is a placebo of normal saline.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
1. The proportion of patients with clinical or electrographic seizures after intervention
2. The proportion of patients with abnormal motor posturing after intervention
3. The proportion of patients with neuro-cognitive deficits three months after discharge

Secondary outcome measures
1. Mortality in either group
2. Proportion of children who develop status epilepticus after intervention
3. Frequency and types of adverse events
4. Mean duration of seizures that occur after the intervention
5. Changes in cerebral blood flow velocity in the middle cerebral artery during seizure episodes
6. Time to regain full consciousness
7. Duration of hospitalisation
8. Neurocognitive deficits at 24 months

The sample of 500 (i.e. 250 in each arm) has a 90% power at 5% level of significance to detect the following changes after allowing for a 20% loss to follow up and death:
a. A 50% reduction (from 27 to 13.5%) in patients with at least one seizure lasting more than five minutes or more than three seizures of any duration
b. A 50% reduction (from 34 to 17%) in patients who will develop abnormal motor posturing
c. A 50% reduction in cognitive impairment from 24 to 12% as measured by Evoked Response Potentials (ERP).

An interim analysis is planned after 200 children have been recruited into the trial.

Overall study start date
28/12/2004

Completion date
31/12/2009

Eligibility

Key inclusion criteria
1. Children who are unable to localise a painful stimulus 30 minutes after a seizure or correction of hypoglycaemia
2. Written informed consent from the parents or guardian
3. Age 9 months to 13 years

Participant type(s)
Patient

Age group
Child

Lower age limit
9 Months

Upper age limit
13 Years

Sex
Both

Target number of participants
500

Key exclusion criteria
1. Children with a history of epilepsy, significant developmental delay, cerebral palsy, or sickle cell disease
2. Children who would have received phenytoin for treatment of seizures before recruitment
3. Evidence of head trauma

Date of first enrolment
28/12/2004

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
England

Kenya

United Kingdom

Study participating centre
University College London
London
United Kingdom
WC1N 2AP

Sponsor information

Organisation
University College London (UK)

Sponsor details
Institute of Child Health
30 Guilford Street
London
England
United Kingdom
WC1N1EH

Sponsor type
University/education

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

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

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