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

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

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

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#### Contact details

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# Additional identifiers

Protocol serial number 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

# Study type(s)

Prevention

# 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(s)

- 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

#### Key secondary outcome(s))

- 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.

#### 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 quardian
- 3. Age 9 months to 13 years

# Participant type(s)

Patient

# Healthy volunteers allowed

No

# Age group

Child

# Lower age limit

9 months

# Upper age limit

13 years

#### Sex

All

#### 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

**United Kingdom** 

England

Kenya

# Study participating centre University College London

London United Kingdom WC1N 2AP

# **Sponsor information**

#### Organisation

University College London (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**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration