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A randomised controlled trial of phenobarbitone and phenytoin for newly diagnosed epilepsy in adults

Submission date
07/07/2007

Registration date
17/07/2007

Last Edited
27/06/2008

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Nervous System 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
KEMRI SCC 786

Study information

Scientific Title

Acronym
AEPEP

Study objectives
To compare the frequency of side effects of phenobarbitone to those of phenytoin as first line treatment of active convulsive epilepsy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Kemri/National Ethical Review Committee reviewed the proposal, and permission was granted on 21st June 2007 (ref: SSC 786).

Study design
Open label randomised trial of phenobarbitone versus phenytoin

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Epilepsy

Interventions
Phenobarbitone versus phenytoin, in which the assessor is blinded to the treatment allocation and patient is given information on the side effects of both anti-epileptic drugs together, but is not aware which side effects is attributed to which drug.

Treatment:
The following regimens for the drugs will be used:

Phenobarbitone: adults will be started on 60 mg daily orally in the evening, increasing to 120 mg daily after two weeks. Thereafter the dose will be titrated according to the response and side effects. If seizures are not controlled (greater than one per week) by six months after enrolling into the trial, the subject will be started on phenytoin.

Phenytoin: adults will be started on 50 mg daily, increasing to 100 mg daily (in two doses one in the morning and one in the evening). Thereafter the dose will be titrated according to the response and side effects. If seizures are not controlled (greater than one per week) by six months after enrolling into the trial, the subject will be started on phenobarbitone.

If both drugs prove to be ineffective, i.e., continued seizures after substitution with the other study drug then the subject will be started on dual therapy.

Monitoring:
All subjects will be seen a month after enrolment into the study, when they will be assessed by a clinician and the dosage of the drug adjusted according to clinical response and side effects. Blood and saliva samples will be taken for concentrations of the Antiepileptic Drug (AED), but the results will only be available at the subsequent visit.

Thereafter subjects will be seen at 3 months, 6 months and 12 months after starting treatment. At each visit, the subjects will be seen by a fieldworker (blinded to the treatment group), who will administer a Quality Of Life (QOL) questionnaire. Thereafter the subject will be seen by a clinician who will manage the epilepsy according to standard medical practice.

Subjects will also be asked to bring in the bottle of tablets so that they can be counted, and the excess tablets will be used to aid in estimation of compliance. Furthermore subjects will be visited at home by a designated fieldworker (maximum of 14 visits per day) to promote adherence.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Phenobarbitone, phenytoin

Primary outcome measure
Frequency of side effects.

Secondary outcome measures
1. Time to next seizure after starting treatment using an epilepsy history questionnaire
2. Seizure frequency: frequency of seizures will be monitored using seizure calendars, which the subjects will be educated on keeping
3. Compliance with drugs: drug compliance will be assessed by direct measurement of drug levels in blood at the initial contact and at 12 months; and using saliva samples at the end of 1, 3, 6 and 12 months. This will be reinforced by tablet counting and information elicited from patients/caregivers

4. Quality of life measure as developed for this proposal
5. Cognitive effects: subjects will have a culturally appropriate test of cognitive function performed at 6 months and 1 and 3 years afterwards

Overall study start date
09/07/2007

Completion date
31/12/2011

Eligibility

Key inclusion criteria
Adults (greater than 17 years) with active epilepsy, i.e. two or more seizures within the last year and the following seizure types:
1. Tonic-clonic
2. Partial becoming generalised
3. Partial motor

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
300

Key exclusion criteria
1. Subjects who have received antiepileptic drugs in the past
2. Subjects with absence, myoclonic or atonic seizures
3. Subjects with progressive neurological disease
4. Subjects with severe learning difficulties
5. Less than 18 years old

Date of first enrolment
09/07/2007

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
Kenya

Study participating centre
P.O. Box 230
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Sponsor information

Organisation
University of Oxford (UK)

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Sponsor type
University/education

Website
http://www.ox.ac.uk/

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
The Wellcome Trust (UK) (grant ref: 077092)

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