ISRCTN28271641 https://doi.org/10.1186/ISRCTN28271641

Indications for and consequences of antiepileptic drug withdrawal

Submission date	Recruitment status	[ ] Prospectively registered
30/06/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
17/08/2006	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
25/09/2009	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Pål Gulbrandsen

Contact details
HØKH
Akershus University Hospital
Mail drawer 95
Lørenskog
Norway
1478
+47 (0) 67 92 94 61
pal.gulbrandsen@ahus.no

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
We will investigate predictors for remission of seizures after Anti-Epileptic Drug (AED) withdrawal. We also will monitor: seizure frequency, cardiovascular function, hormonal function, cognitive function, quality of life, and Electroencephalogram (EEG).

Ethics approval required
Old ethics approval format

Ethics approval(s)
The regional committee for medical research ethics in Eastern Norway has approved the study protocol (reference: S-127/99-99044).

Study design
Randomised controlled double-blinded study

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
The patients were block-randomised (in blocks of ten) to receive blindly either active medication or placebo in pre-packed dispensers (Dosett), one for each of the 12 withdrawal weeks. Those randomised to withdrawal had AED dose reduction by 20 percent the first six weeks and 20 percent every second week until week 12. The reduced medication was substituted with a placebo to keep the study double blinded.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Carbamazepine, Valproate, Phenytoin, Lamotrigine and Phenobarbitol.

Primary outcome measure
1. Neuropsychological function, as measured by a battery of 15 tests
2. Seizures

Secondary outcome measures
1. Electrocardiogram (ECG)
2. Electroencephalogram (EEG)
3. Endocrine function
4. Quality of life
5. Blood lipid levels

Overall study start date
01/09/1999

Completion date
31/03/2005

Eligibility

Key inclusion criteria
1. Epilepsy (minimum of two unprovoked epileptic fits)
2. Two year seizure freedom
3. Only one antiepileptic drug in use
4. Aged 18 to 67 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
160 (150-170)

Key exclusion criteria
1. Juvenile myoclonus epilepsy
2. Paroxysmal EEG activity before termination of treatment, in patients with primary generalized epilepsy
3. Using several AEDs
4. Pregnancy
5. Mental retardation

6. Progressive neurological disease
7. Other known condition, which may affect patient's condition during follow-up
8. Other permanent medication (except in the case of contraceptive pills and hormonal treatment for menopausal conditions)

Date of first enrolment
01/09/1999

Date of final enrolment
31/03/2005

Locations

Countries of recruitment
Norway

Study participating centre
HØKH
Lørenskog
Norway
1478

Sponsor information

Organisation
Akershus University Hospital (Norway)

Sponsor details
Mail drawer 95
Lørenskog
Norway
1478
+47 (0) 67 92 92 35
geir.bukholm@ahus.no

Sponsor type
Hospital/treatment centre

Website
http://www.ahus.no/modules/module_123/proxy.asp?iDisplayType=2&iCategoryId=474&iInfoId=2906&mids=1034

ROR
https://ror.org/0331wat71

Funder(s)

Funder type
University/education

Funder Name
Akershus University Hospital

Funder Name
The Norwegian Foundation for Health and Rehabilitation

Funder Name
Extra funding is received from:

Funder Name
Norwegian Epilepsy Association

Funder Name
Norwegian Chapter of the International League against Epilepsy

Funder Name
Helse Øst Regional Health Authorities

Funder Name
Foundation for Health Services Research (HELTEF)

Funder Name
The various active drugs and placebo tablets were provided by Glaxo SmithKline, Desitin and Novartis

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?
Results article	results	01/03/2008		Yes	No