Indications for and consequences of antiepileptic drug withdrawal

Submission date	Recruitment status No longer recruiting	Prospectively registered	
30/06/2006		☐ Protocol	
Registration date 17/08/2006	Overall study status Completed	Statistical analysis plan	
		[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

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Additional identifiers

Protocol serial number 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

Study type(s)

Treatment

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(s)

- 1. Neuropsychological function, as measured by a battery of 15 tests
- 2. Seizures

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

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

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