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A randomised controlled trial of longer-term clinical outcomes and cost-effectiveness of Standard And New Antiepileptic Drugs

Submission date
25/04/2003

Recruitment status
No longer recruiting

Registration date
25/04/2003

Overall study status
Completed

Last Edited
14/04/2020

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
HTA 95/13/01

Study information

Scientific Title
A randomised controlled trial of longer-term clinical outcomes and cost-effectiveness of Standard And New Antiepileptic Drugs

Acronym
SANAD

Study objectives
We propose a pragmatic parallel group Randomised Controlled Trial (RCT) comparing monotherapy with clinicians' first choice standard drug (carbamazepine or valproate) versus appropriate comparators from among the new antiepileptic drugs.

More details can be found at http://www.nets.nihr.ac.uk/projects/hta/951301

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)
Treatment

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

Interventions
Monotherapy with clinicians' first choice standard drug (carbamazepine or valproate) versus appropriate comparators from among the new antiepileptic drugs

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Carbamazepine, valproate

Primary outcome(s)
Primary outcomes will be retention time on randomised drug and time to one year remission of seizures.

Key secondary outcome(s))

Secondary outcomes will include psychosocial measures and impact on direct medical costs.

Completion date
31/03/2006

Eligibility

Key inclusion criteria
Patients recently suffering seizures

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Total final enrolment
2437

Key exclusion criteria
Not provided at time of registration.

Date of first enrolment
01/09/1998

Date of final enrolment
31/03/2006

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Walton Centre
Liverpool
United Kingdom
L9 7LJ

Sponsor information

Organisation
Department of Health (UK)

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

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	carbamazepine trial results	24/03/2007		Yes	No
Results article	valproate trial results	24/03/2007		Yes	No
Results article	results	01/03/2015		Yes	No
Results article	results	01/04/2019		Yes	No
Other publications	HTA monograph	01/10/2007		Yes	No