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

Submission date	Recruitment status	[ ] Prospectively registered
25/04/2003	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
25/04/2003	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
14/04/2020	Nervous System Diseases	

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
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

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
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 measure
Primary outcomes will be retention time on randomised drug and time to one year remission of seizures.

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

Overall study start date
01/09/1998

Completion date
31/03/2006

Eligibility

Key inclusion criteria
Patients recently suffering seizures

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
3,000

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
England

United Kingdom

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

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Quarry House
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Sponsor type
Government

Website
http://www.dh.gov.uk/en/index.htm

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name

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