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Antidyskinetic properties of topiramate: a double-blind, placebo-controlled trial in patients with Parkinson's disease and levodopa-induced dyskinesias

Submission date 20/05/2008	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 02/07/2008	**Overall study status** Completed	
Last Edited 09/05/2016	**Condition category** 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

Protocol serial number
2007 Neuro 12

Study information

Scientific Title
Antidyskinetic properties of topiramate: a double-blind, placebo-controlled trial in patients with Parkinson's disease and levodopa-induced dyskinesias

Study objectives
Levodopa therapy is effective for the motor symptoms of Parkinson's disease. However, around half of patients develop abnormal involuntary movements, or dyskinesia, after 4 - 6 years of treatment. Current treatment interventions for this are not satisfactory in all cases.

Hypothesis:
Topiramate administration will attenuate levodopa-induced dyskinesia in patients with Parkinson's disease (PD) without worsening parkinsonism.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leeds (West) Research Ethics Committee, 24/01/2008, ref: 07/H1307/205

Study design
Multicentre, randomised, double-blind, placebo-controlled, crossover study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Parkinson's disease and levodopa-induced dyskinesia

Interventions
This is a randomised, crossover study.

Topiramate group: start dose 25 mg/day orally (p.o.), to be up-titrated by 25 mg/day weekly to target dose of 100 mg/day in two divided doses. Participants to stay on maintenance dose for two weeks prior to assessment. Participants will attend having not taken usual morning medications, and response to these medications will then be assessed.

Control: placebo capsules, identical in appearance. To be titrated on same schedule as topiramate.

Following a two-week down-titration period, there will be a further two-week washout period before crossover.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Topiramate

Primary outcome(s)
Investigator-rated dyskinesia severity. To be scored by a blinded assessor from video recordings of participants, every 30 minutes for a total of 150 minutes. Dyskinesia to be rated at each time-point using a 5-point objective dyskinesia intensity rating scale, rating seven body parts (each limb, face, trunk and neck) with a maximum possible score of 28 at each time point. Timepoints of assessment: baseline (week 0), end of Arm 1 (week 6) and end of Arm 2 (week 16)

Key secondary outcome(s))
1. Investigator-rated parkinsonism. Unified Parkinson's Disease Rating Scale (UPDRS) part III to be assessed at 30-minute intervals during clinical assessment. Timepoints of assessment: week 0, 6 and 16.
2. Subject-rated dyskinesia severity:
2.1. Lang-Fahn Activities of Daily Living Dyskinesia Scale. Timepoints of assessment: week 0, 6, and 16.
2.2. Clinical Global Impression of change, assessed weekly during dose titration and at weeks 6 and 16
2.3. UPDRS Part IV. Timepoints of assessment: week 0, 6 and 16.
3. Effects on mood and activities of daily living:
3.1. UPDRS Part I, II. Timepoints of assessment: week 0, 6 and 16.
3.2. Geriatric Depression Scale-15. Timepoints of assessment: week 0, 2, 4, 6, 10, 12, 14 and 16.
4. Excessive daytime sleepiness: Epworth Sleepiness Scale. Timepoints of assessment: week 0, 2, 4, 6, 10, 12, 14 and 16.

Completion date
01/01/2010

Eligibility

Key inclusion criteria
1. Both males and females, no age limits
2. Patients with Parkinson's disease as defined by UK Parkinson's Disease Society Brain Bank criteria
3. Current use of levodopa, dose to be stable for one month prior to enrolment
4. Stable levodopa-induced dyskinesias

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
All

Key exclusion criteria
1. Hypersensitivity to topiramate or its excipients
2. Prior surgery for PD
3. Hoehn and Yahr score of 5 when "off"
4. Dementia
5. History of nephrolithiasis, renal impairment, liver disease, glaucoma
6. Pregnancy and breastfeeding
7. Premenopausal females and males not using adequate contraception
8. Use of other antiepileptic drugs, carbonic anhydrase inhibitors, metformin, digoxin or illicit drugs

Date of first enrolment
01/07/2008

Date of final enrolment
01/01/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Salford Royal NHS Foundation Trust
Salford
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Sponsor information

Organisation
Salford Royal NHS Foundation Trust (UK)

ROR
https://ror.org/019j78370

Funder(s)

Funder type
University/education

Funder Name
University of Manchester (UK)

Alternative Name(s)
University of Manchester in United Kingdom, University of Manchester UK, The University of Manchester, UoM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration