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Randomised controlled trial of carbamazepine assisted detoxification in patients with benzodiazepine dependence

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 27/10/2015	**Condition category** Mental and Behavioural Disorders	

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
N0133160479

Study information

Scientific Title
Randomised controlled trial of carbamazepine assisted detoxification in patients with benzodiazepine dependence

Study objectives
1. Carbamazepine minimizes severity and incidence of benzodiazepine withdrawal symptoms.
2. Carbamazepine assisted detoxification increases the abstinence rates of benzodiazopines in short term.

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
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Mental and Behavioural Disorders: Addiction

Interventions
1. Carbamazepine assisted benzodiazepine detox for 2 weeks
2. Traditional gradual withdrawal of diazepam

Observers will be blinded from allocation of groups. Analysis of Variance (ANOVA) will be used to compare 2 groups.

Intervention Type
Drug

Phase

Not Applicable

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

Primary outcome measure
1. Benzodiazepine withdrawal symptom questionnaire (30 items)
2. Hamilton Depression Rating Scale (17 items) HAM-D)
3. Hamilton Anxiety Rating Scale (HAM-A)
4. Abstinence rates from benzodiazepines

Patients will be assessed at 3 points:
1. Baseline
2. 1 week after starting the detoxification
3. 2 weeks (end of detoxification)

Follow-up interview or phone call will be made 4 weeks after discharge asking if patient are abstinent from benzodiazepines.

Secondary outcome measures
Not provided at time of registration

Overall study start date
21/09/2004

Completion date
30/05/2006

Eligibility

Key inclusion criteria
Patients (18-65 years) who are admitted to Wentworth House or Kenyon House in-patient units, and are using daily doses of benzodiazepine for at least 3 months.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants

Target total for recruitment: 50

Key exclusion criteria
1. Significant psychiatric disorders (by ICD 10)
2. History of or current liver failure
3. Current Alanine Transaminase (ALT) > or equal 150 IU/l in serum LFT
4. Current suicidal ideation
5. Patients who are already on Carbamazepine before referral for In Patient treatment.

Date of first enrolment
21/09/2004

Date of final enrolment
30/05/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Wentworth House
Salford
United Kingdom
M30 9HF

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Bolton, Salford and Trafford Mental Health NHS Trust (UK), NHS R&D Support Funding

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