

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

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

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
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 benzodiazepines 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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

All

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

United Kingdom

England

Study participating centre

Wentworth House

Salford

United Kingdom

M30 9HF

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Government

Funder Name

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

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration