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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Chris Daly

Contact details

Wentworth House Mental Health Services of Salford 8 Westminster Road Eccles Salford United Kingdom M30 9HF

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 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

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

Αll

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

Study outputs

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet Participant information sheet 11/11/2025 No Yes