

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

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

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 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

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

79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

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