ISRCTN69763877 https://doi.org/10.1186/ISRCTN69763877

Reducing long-term benzodiazepine use: effectiveness and cost-effectiveness of two minimal interventions and development of guidelines for case management

Submission date
23/01/2004

Recruitment status
No longer recruiting

Registration date
23/01/2004

Overall study status
Completed

Last Edited
12/04/2012

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Nick Heather

Contact details
Centre for Alcohol and Drug Studies
Northern Regional Alcohol & Drug Service
Plumer Court
Carliol Square
Newcastle upon Tyne
United Kingdom
NE1 6UR
+44 (0)191 219 5648

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PCC16 T84 8846

Study information

Scientific Title
Not provided at time of registration

Study objectives
Recent studies have shown that two inexpensive interventions (a brief GP consultation and a letter from the patients GP) can be effective in leading to reduced benzodiazepine (BZD) intake in long-term users. In a randomised controlled trial, we will directly compare the effectiveness and cost-effectiveness of these two interventions and search for patient and other variables predictive of successful and unsuccessful response to intervention. We will then use the results to develop a set of guidelines for rational deployment of three levels of intervention against long-term BZD use:
1. A GP letter advising gradual reduction
2. A short GP consultation plus self-help booklet
3. Specialised intervention at a benzodiazepine withdrawal clinic

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)
Hospital

Study type(s)
Quality of life

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
Depression, anxiety, neuroses

Interventions

1. A brief GP consultation
2. A letter from the GP advising gradual reduction

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
Effectiveness in curtailing long term use of benzodiazepines and cost-effectiveness of the two interventions.

The main outcome measure was change in BZD intake between the six-month periods before and after the intervention. This was taken from practice prescription records and was available for all 273 patients entering the analysis. BZD intake for each patient was converted to a standard measure of 10 mg diazepam equivalents (Ashton, 1994).

Secondary outcome measures
A subsidiary outcome measure was whether or not the patient was a "true reducer", defined as having reduced BZD intake by a quarter or more, including those who had stopped intake completely.

Overall study start date
24/03/1997

Completion date
23/03/1999

Eligibility

Key inclusion criteria
Patients on benzodiazepines.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
284

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
24/03/1997

Date of final enrolment
23/03/1999

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Centre for Alcohol and Drug Studies
Newcastle upon Tyne
United Kingdom
NE1 6UR

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
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.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive Northern and Yorkshire (UK)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2001		Yes	No