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Clinical trial on the efficacy of two interventions for discontinuing long term benzodiazepine use in primary care

Submission date
17/06/2010

Recruitment status
No longer recruiting

Registration date
27/07/2010

Overall study status
Completed

Last Edited
18/02/2014

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PS09/00947

Study information

Scientific Title
A cluster randomised controlled trial on the efficacy of a structured educational intervention or minimal intervention versus usual care for discontinuing long term benzodiazepine use in primary care

Acronym
BENZORED

Study objectives
Although short-term efficacy of benzodiazepines (BZD) is well established, long-term efficacy remains controversial and long term use is usually not recomended because of potential adverse effects and the risks of tolerance and dependence, increased risk of hip fractures, motor vehicle accidents and memory impairments. Most guidelines recommend restricting their use to short periods only, but nevertheless they are widely prescribed.

Objective:
To evaluate the efficacy of a structured educative intervention (SEI) and of a minimal intervention (MI) performed by the family General Practitioner (GP) to discontinue long term BZD use, compared to usual care. To evaluate the safety of these interventions in anxiety and depression symptoms, sleep quality and alcohol consumption.

Hypotheses:
1. In primary care patients on long-term benzodizapine, a structured educational intervention results in a cessation rate of 40% after one year, compared to 25% with minimal intervention and less than 10% with usual care
2. The interventions proposed (EI and MI) do not induce more symptoms of anxiety and depression or affect quality of sleep and alcohol consumption compared to the control group

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethics Committee of the Balearic Islands (Comité Ético Investigación Clínica [CEIC])approved on the 29th April 2009

Study design
Multicentre cluster randomised controlled three-arm parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)

Other

Participant information sheet
Not available in web format, please contact Mr Alfonso Leiva Rus [aleiva@ibsalut.caib.es] to request a patient information sheet

Health condition(s) or problem(s) studied
Benzodiazepine use, reduction and withdrawal

Interventions
Patients were randomised to one of three groups, comparing two strategies for the reduction of chronic bendzodizepine and a control group:
1. Structured educational intervention: 1 educational interview (20 - 25 minutes) which addresses some specific aspects of chronic use of benzodiazepines with a pattern of gradual dose reduction of benzodiazepine and 4 - 6 subsequent follow-up visits to control the gradually descending dose
2. Minimal intervention: 1 educational interview (20 - 25 minutes) which addresses some specific aspects of chronic use of benzodiazepines with written information on the pattern of gradually reducing the dosage of benzodiazepine
3. Control group: usual clinical practice, no intervention visits

There will be follow up visits at 6 and 12 months, of 35 minutes duration.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Benzodiazepine use at 12 months

Secondary outcome measures
1. Anxiety and Depression Scale
2. Quality of Sleep Scale
3. Alcohol consumption

Outcomes will be measured at baseline, 6 and 12 months.

Overall study start date
15/07/2010

Completion date
15/10/2012

Eligibility

Key inclusion criteria
1. Patients between 18 and 80 years
2. Recorded history of benzodiazepine consumption or an analogue at least 5 times a week for

at least six months
3. A minimum of 6 months prescription of a benzodiazepine or similar

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Total sample size is 495 patients from primary health care centres in three Spanish regions

Key exclusion criteria
1. Patients with severe anxiety or depressive disorder, psychotic disorder, severe personality disorder, and/or psychiatric monitoring
2. Patients with cognitive impairment, terminal illness or serious medical conditions, illegal drug use or abuse alcohol, inability to sign informed consent
3. Institutionalised patients
4. Patients with exacerbation of symptoms of anxiety/depression whose doctor considers that the withdrawal of a benzodiazepine can be harmful at this time
5. Patients with limited capacity for understanding
6. Patients that have participated in a clinical research study during the last 3 months

Date of first enrolment
15/07/2010

Date of final enrolment
15/10/2012

Locations

Countries of recruitment
Spain

Study participating centre
C/ Matamusinos, 22 (Ponent-Son Serra-La Vileta)
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Sponsor information

Organisation
Health Service of the Balearic Islands (Servei de Salut de les Illes Balears [IB-salut]) (Spain)

Sponsor details
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Sponsor type
Government

ROR
https://ror.org/00d9y8h06

Funder(s)

Funder type
Government

Funder Name
Health Research Fund (Fondo de Investigaciones Sanitarias [FIS]) (Spain)

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?
Protocol article	protocol	20/04/2011		Yes	No

Results article	results	01/06/2014	Yes	No