ISRCTN80847419 https://doi.org/10.1186/ISRCTN80847419

Exploratory trial of antidepressant therapy for dizziness

Submission date 30/09/2005	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/09/2005	**Overall study status** Stopped	
Last Edited 20/09/2013	**Condition category** Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Irwin Nazareth

Contact details
Royal Free and University College Medical School
Royal Free Campus
Rowland Hill Street
London
United Kingdom
NW3 2PF
+44 (0)20 7830 2394
I.nazareth@ucl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0530147182

Study information

Scientific Title

Study objectives
In primary care attendees with symptoms of dizziness and associated psychological symptoms, a) antidepressants and b) vestibular rehabilitation exercises reduces symptoms of dizziness when either treatment is delivered singly or together in a factional design. Prior to testing this hypothesis, in this study the researchers propose to conduct an exploratory trial in which they will examine the effects of varying doses of antidepressants, on the symptoms of dizziness amongst general practice attendees visiting their GP for this purpose.

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)
GP practice

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Signs and Symptoms: Dizziness

Interventions
1. Low dose antidepressant (Citalopram) therapy and self-help leaflet
2. Full dose antidepressant (Citalopram) and self-help leaflet
3. A control group receiving no antidepressant treatment, but receiving self-help leaflet

Added 20/09/2013: this trial never took place as there was no sponsorship agreed.

Intervention Type
Drug

Phase

Not Specified

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

Primary outcome measure
The community prevalence of dizziness ranges from 16-35%. One quarter of such sufferers report chronic handicapping symptoms and psychological distress. There are currently no evaluations of treatment for dizziness in the community. This study is the first step in evaluating a treatment that has been previously examined in a hospital setting.
This study will provide:
1. Information on the acceptability and feasibility of using antidepressants for people with dizziness in primary care.
2. Estimates of the numbers of people with dizziness who can be recruited to the study from each practice and hence assist with planning in a main trial.
3. Information on people's preferences for each intervention.
4. Preliminary estimates of the effect on clinical, psychological and physical outcomes in people with dizziness in primary care treated with low dose or full dose of antidepressants, which will inform sample size calculations for a main trial.
In addition, the results of this study will allow the researchers to finalise their assessment and treatment schedule for people with dizziness in primary care.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/06/2003

Completion date
31/05/2005

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria
GP attendees with acute symptoms of dizziness, vertigo, lightheadedness, dysequilibrium, presyncope, and other types of balance problems for more than 2 months, associated with associated psychological symptoms.

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
48-64 participants

Key exclusion criteria
1. Below 18 years old and above 85 years old
2. Too ill to take part (i.e serious physical illness or terminal disorder)
3. First episode of dizziness
4. Acute dizziness
5. Vetebrobasilar insufficiency
6. Cardivascular diagnoses
7. Severe neurological disorders

Date of first enrolment
01/06/2003

Date of final enrolment
31/05/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Free and University College Medical School
London
United Kingdom
NW3 2PF

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
North Central London Research Consortium (UK) NHS 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