ISRCTN55819922 https://doi.org/10.1186/ISRCTN55819922

Effect of paroxetine treatment on glycaemic control and quality of life in mildly depressed type two diabetic subjects: a double-blind randomised placebo controlled six month trial

Submission date
02/08/2006

Recruitment status
No longer recruiting

Registration date
13/09/2006

Overall study status
Completed

Last Edited
26/06/2007

Condition category
Nutritional, Metabolic, Endocrine

[_] 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
Prof Kristian Wahlbeck

Contact details
Psychiatric unit
Vaasa Central Hospital
Vaasa
Finland
FIN-65130
kristian.wahlbeck@stakes.fi

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Study objectives
We hypothesised that paroxetine will have a beneficial effect on quality of life and on glycaemic control in mildly depressed diabetics.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Helsinki University Central Hospital ethics review committee has approved the study in 2001

Study design
Randomised double-blind placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Type two diabetes mellitus and depression.

Interventions
Paroxetin 20 mg per day or placebo for six months. Blood samples and clinical examination four times during the trial.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
10% decrease in HbA1c.

Secondary outcome measures
20% improvement in quality of life as defined by the RAND-36 health relate quality of life questionnaire.

Overall study start date
01/06/2001

Completion date
20/12/2002

Eligibility

Key inclusion criteria
1. Volunteers between 50 and 70 years of age
2. Diagnosed type two diabetes
3. Hba1c more than 7.0%
4. Mild symptoms of depression

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
38

Key exclusion criteria
1. Moderate to severe depression based on Diagnostic and Statistical Manual of mental disorders (DSM-IV) criteria
2. Severe diabetic complications
3. Use of warfarin
4. Glaucoma

Date of first enrolment
01/06/2001

Date of final enrolment
20/12/2002

Locations

Countries of recruitment
Finland

Study participating centre
Psychiatric unit
Vaasa
Finland
FIN-65130

Sponsor information

Organisation
GlaxoSmithKline (Finland)

Sponsor details
Piispansilta 9 A
3 krs.
Espoo
Helsinki
Finland
02230
terese.m.pfister-peltola@sb.com

Sponsor type
Industry

ROR
https://ror.org/01jxkq910

Funder(s)

Funder type
Industry

Funder Name
Funded by GlaxoSmithKline

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:	15/06/2007		Yes	No