

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

☐ Prospectively registered

☐ Protocol

Registration date

13/09/2006

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

26/06/2007

Condition category

Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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
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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