

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

Registration date
13/09/2006

Overall study status
Completed

Protocol

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

Protocol serial number

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

Study type(s)

Treatment

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(s)

10% decrease in HbA1c.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

ROR

<https://ror.org/01jxkq910>

Funder(s)

Funder type

Industry

Funder Name

Funded by GlaxoSmithKline

Results and Publications

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