

Realisation of established targets for patients with diabetes type 2 at primary care setting

Submission date
19/12/2005

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
19/12/2005

Overall study status
Completed

☐ Statistical analysis plan

☐ Results

Last Edited
03/07/2008

Condition category
Nutritional, Metabolic, Endocrine

☐ Individual participant data

☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

NTR391

Study information

Scientific Title

Acronym

Feistritz-trial

Study objectives

Targets of blood pressure, glucose and cholesterol are more feasible with rosiglitazone and structured treatment advice.

Please note that as of 03/07/2008 more details on the sources of funding have been added to this record. This can be seen below in the sources of funding section.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee.

Primary study design

Interventional

Study design

Multicentre, randomised, placebo controlled, parallel group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Diabetes mellitus type II (DM type II)

Interventions

Two treatment arms:

Arm A: Addition of rosiglitazone 8 mg once daily (od) or

Arm B: No addition of rosiglitazone

For each patient a regimen of treatment will be arranged concerning the glucose, blood pressure and cholesterol targets.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Rosiglitazone

Primary outcome(s)

The total amount of targets reached with treatment with rosiglitazone compared with treatment with no rosiglitazone.

Key secondary outcome(s)

The outcome of glitazone on the recently discovered risk factors of diabetic patients.

Completion date

01/01/2010

Eligibility

Key inclusion criteria

1. Patients with type 2 diabetes
2. Signed informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Aged less than 18 years
2. Quality-adjusted life years (QALY) less than 5 years
3. Use of insulin, fibrates or thiazolidines less than 6 weeks before inclusion
4. Heart failure, New York Heart Association (NYHA) class II or more
5. Myocardial infarction (MI), angina pectoris (AP), transient ischaemic attack (TIA) or cerebrovascular attack (CVA) less than 3 months before randomisation
6. Surgery, severe trauma or infection less than 3 months before randomisation
7. Known liver disease or alanine aminotransferase (ALT), aspartate aminotransferase (AST), gamma glutamyltransferase (GT) greater than three times upper limit
8. Serum creatinine greater than 150 mmol/l
9. Triglycerides greater than 8 mmol/l

Date of first enrolment

01/12/2003

Date of final enrolment

01/01/2010

Locations

Countries of recruitment

Netherlands

Study participating centre

Diakonessenhuis Utrecht/Zeist

Zeist

Netherlands
3700 BA

Sponsor information

Organisation

Aventis (The Netherlands)

ROR

<https://ror.org/00pgqb537>

Funder(s)

Funder type

Industry

Funder Name

Added on 03/07/2008:

Funder Name

Grants from:

Funder Name

GlaxoSmithKline (The Netherlands)

Alternative Name(s)

GlaxoSmithKline plc., GSK plc., GlaxoSmithKline plc, GSK

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United Kingdom

Funder Name

Sanofi-Aventis (The Netherlands)

Funder Name

Merck Sharp and Dohme (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary