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

Submission date	Recruitment status	[ ] Prospectively registered
19/12/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/12/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
03/07/2008	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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.

Study design
Multicentre, randomised, placebo controlled, parallel group trial

Primary study design
Interventional

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