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Does treatment with rosiglitazone result in improved pancreatic beta-cell function as compared to glimepiride in metformin treated diabetes type 2 patients?

Submission date
08/03/2006

Recruitment status
No longer recruiting

Registration date
08/03/2006

Overall study status
Completed

Last Edited
04/11/2008

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
NTR605

Study information

Scientific Title

Study objectives
By inducing a shift of fat out of the visceral compartment - among which the pancreas - into the subcutaneous compartment, rosiglitazone results in improved pancreatic beta-cell function in type 2 diabetes patients, as compared to a sulfonylurea derivative, while both groups continue metformin treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from local medical ethics committee

Study design
Randomised active 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
Patients will be randomised to 26 weeks of treatment with metformin with glimepiride 4 mg a day or metformin with rosiglitazone 8 mg a day. Before the start of the treatment patients will undergo a 200 minute hyperglycaemic (aiming at 15 mmol/l) clamp with administration of glucagon-like peptide-1 (GLP-1) starting at 120 minutes and an arginine bolus at 180 minutes to elicit a further beta-cell response. Twenty-six weeks later, the assessments will be repeated, again on metformin, other study medication taken until the morning before this assessment.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Rosiglitazone, glimepiride, metformin, glucagon-like peptide-1, arginine

Primary outcome(s)
The peak insulin concentrations during the hyperglycaemic clamp protocol.

Key secondary outcome(s))
No secondary outcome measures

Completion date
01/04/2007

Eligibility

Key inclusion criteria
1. Informed consent form signed
2. Type 2 diabetes patients, according to World Health Organization (WHO) criteria
3. Age 18 - 70 years
4. Use of metformin, at least 500 mg a day
5. HbA1c greater than 7.0% inclusive when on metformin alone, or greater than 6.5% when on combination therapy of metformin and a sulfonylurea derivative. Use of a sulfonylurea derivative is allowed, with a wash-out period of four weeks before the first assessments.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Established coronary heart disease
2. Previous use of a thiazolidinedione

Date of first enrolment
01/09/2004

Date of final enrolment
01/04/2007

Locations

Countries of recruitment
Netherlands

Study participating centre

Academic Medical Centre
Amsterdam
Netherlands
1100 DD

Sponsor information

Organisation
Academic Medical Centre (AMC) (The Netherlands)

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Industry

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary