A 52 week double blind randomized controlled trial comparing the effect of Rosiglitazone versus Placebo on the prevention of progression of atherosclerosis in high risk patients without diabetes.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24183

Source
NTR

Brief title
RUBENS

Health condition

Metabolic Syndrome

Sponsors and support

Primary sponsor: LUMC
Source(s) of monetary or material Support: Partially financed by an unconditional grant GSK

Intervention

Outcome measures

Primary outcome

Magnetic resonance (MR) assessment of the carotid artery wall, MR-measured hepatic, intra-abdominal and peripheral subcutaneous fat stores.

Secondary outcome

1. Assessment of the changes in selected inflammatory and metabolic parameters amongst which changes in insulin resistance & iNOS;

2. Cross sectional assessment of the relation between the characteristics of the Magnetic Resonance image of the carotid arterial wall and Circulating Endothelial Progenitor cells;

3. The effect of Rosiglitazone on CEPs after one year of treatment in subjects with high cardiovascular risk without diabetes mellitus;

4. Optimalisation of MR assessment of (complex) atherosclerotic plaques & other cardiovascular risk markers.

Study description

Background summary

To study the effects of rosiglitazone on the prevention of progression of atherosclerosis, and on selected inflammatory, metabolic and anthropometric parameters in high-risk patients with visceral obesity and the metabolic syndrome, without DM2 and Cardiovascular disease.

Study objective

The metabolic syndrome and its visceral adiposity may well be beneficially influenced by PPAR-ã agonist, by redistributing fat mass from central to peripheral stores and improving insulin resistance. The inflammatory atherosclerotic response, as monitored by CRP, may also directly be beneficially influenced by PPAR-ã agonists in human subjects. In addition, we hypothesize that thiazolidinediones will beneficially influence IMT in subjects with the metabolic syndrome as defined by the inclusion criteria.

Study design

N/A

Intervention

1. Lifestyle intervention;

2. Rosiglitazone 8 mg (4 mg bd) versus placebo.

Contacts

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Eligibility criteria

Inclusion criteria

1. Males;

2. Age: males>=50 years;

3. Visceral obesity as determined by Wcr: males: >94cm;

4. Two other metabolic syndrome criteria (According to IDF criteria 2005) and/or a positive family history for cardiovascular disease (CHD and/or PAD in first degree family member: male <55y; female<60y);

5. CRP > 1.8 mg/L;

6. Subject who is willing and is able to provide a signed and dated written informed consent.

Exclusion criteria

1. Severe obesity (BMI>35 kg/m2);

2. Diabetes type 2 defined as fasting venous plasma glucose >7.0 mmol/L, or HbA1c >6.5%;

3. Primary dyslipidemia;

4. A previous cardiovascular event, including Q-wave infarction on electrocardiography (ECG);

5. QTc time interval on baseline ECG > 450ms;

6. Heart failure NYSE class I or higher;

7. Hypoglycaemia;

8. Presence of clinically significant hepatic disease (i.e. subjects with ALT, total bilirubin, or alkaline phosphatase > 2.5 times the upper limit of the normal laboratory range);

9. Subjects with creatinine clearance < 40 mL/min calculated using the Cockcroft-Gault equation adjusted for ideal body weight;

10. Contraindication for MRI-assessments;

11. Risk of non-compliance.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	26-09-2005
Enrollment:	116
Type:	Actual

Ethics review

Positive opinion Date:	09-09-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL269
NTR-old	NTR307
Other	: P04.232
ISRCTN	ISRCTN54951661

Study results

Summary results
N/A