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.

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24183

Bron
NTR

Verkorte titel
RUBENS

Aandoening

Metabolic Syndrome

Ondersteuning

Primaire sponsor: LUMC
Overige ondersteuning: Partially financed by an unconditional grant GSK

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

1. Lifestyle intervention;

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

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	26-09-2005
Aantal proefpersonen:	116
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	09-09-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A