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A 52 week double blind randomised controlled trial comparing the effect of rosiglitazone versus placebo on the prevention of progression of atherosclerosis in high risk patients without diabetes

Submission date 20/12/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/12/2005	**Overall study status** Completed	
Last Edited 05/04/2012	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
P04.232; NTR307

Study information

Scientific Title

Acronym
RUBENS

Study objectives
The metabolic syndrome and its visceral adiposity may well be beneficially influenced by peroxisome proliferator-activated receptor (PPAR)-alpha agonist, by redistributing fat mass from central to peripheral stores and improving insulin resistance. The inflammatory atherosclerotic response, as monitored by C-reactive protein (CRP), may also directly be beneficially influenced by PPAR-alpha agonists in human subjects. In addition, we hypothesise that thiazolidinediones will beneficially influence intima-media thickness (IMT) in subjects with the metabolic syndrome as defined by the inclusion criteria.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local medical ethics committee

Study design
Randomised double blind placebo controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Metabolic syndrome, atherosclerosis

Interventions

1. Lifestyle intervention
2. Rosiglitazone 8 mg (4 mg twice daily [bd]) versus placebo

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Rosiglitazone

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

Secondary outcome measures
1. Assessment of the changes in selected inflammatory and metabolic parameters amongst which changes in insulin resistance and inducible nitric oxide synthase (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 and other cardiovascular risk markers

Overall study start date
26/09/2005

Completion date
01/04/2007

Eligibility

Key inclusion criteria
1. Males
2. Age: males greater than or equal to 50 years
3. Visceral obesity as determined by Wcr: males: greater than 94 cm
4. Two other metabolic syndrome criteria (According to IDF criteria 2005) and/or a positive family history for cardiovascular disease (coronary heart disease [CHD] and/or peripheral arterial disease [PAD] in first degree family member: males less than 55 years; females less than 60 years)
5. CRP greater than 1.8 mg/L
6. Subject who is willing and is able to provide a signed and dated written informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
116

Key exclusion criteria
1. Severe obesity (body mass index [BMI] greater than 35 kg/m^2)
2. Diabetes type 2 defined as fasting venous plasma glucose greater than 70 mmol/L, or HbA1c greater than 65%
3. Primary dyslipidaemia
4. A previous cardiovascular event, including Q-wave infarction on electrocardiography (ECG)
5. QTc time interval on baseline ECG greater than 450 ms
6. Heart failure New York Heart Association (NYHA) class I or higher
7. Hypoglycaemia
8. Presence of clinically significant hepatic disease (i.e., subjects with alanine aminotransferase [ALT], total bilirubin, or alkaline phosphatase greater than 25 times the upper limit of the normal laboratory range)
9. Subjects with creatinine clearance less than 40 mL/min calculated using the Cockcroft-Gault equation adjusted for ideal body weight
10. Contraindication for magnetic resonance imaging (MRI)-assessments
11. Risk of non-compliance

Date of first enrolment
26/09/2005

Date of final enrolment
01/04/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Leiden University Medical Centre (LUMC)
Leiden
Netherlands
2300 RC

Sponsor information

Organisation
Leiden University Medical Centre (LUMC) (Netherlands)

Sponsor details
Albinusdreef 2
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Sponsor type
University/education

Website
http://www.lumc.nl/

ROR
https://ror.org/027bh9e22

Funder(s)

Funder type
Industry

Funder Name
GlaxoSmithKline (Netherlands)

Alternative Name(s)
GlaxoSmithKline plc., GSK plc., GSK

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	28/10/2011		Yes	No