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Effect of valsartan on endothelial function, carotid intima-media thickness, left ventricular mass, arterial compliance, inflammation and coagulation abnormalities in the metabolic syndrome

Submission date	Recruitment status	[ ] Prospectively registered
29/10/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
07/02/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
12/04/2017	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Rajdeep Khattar

Contact details
Consultant Cardiologist
Manchester Heart Centre
Oxford Road
Manchester
United Kingdom
M13 9WL
+44 (0)161 276 6576
rajdeep.khattar@cmmc.nhs.uk

Additional identifiers

EudraCT/CTIS number
2006-006986-18

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
EudraCT Number: 2006-006986-18

Study information

Scientific Title
Effect of valsartan on endothelial function, carotid intima-media thickness, left ventricular mass, arterial compliance, inflammation and coagulation abnormalities in the metabolic syndrome

Study objectives
The study is conducted on patients with metabolic syndrome. The National Cholesterol Education Program Adult Treatment Panel definition of metabolic syndrome will be applied and includes the presence of three or more of the following components:
1. Waist girth greater than 102 cm in men or greater than 94 cm in women
2. Serum triglycerides greater than 1.7 mmol/l
3. Serum High Density Lipoprotein (HDL)-cholesterol less than 1.04 mmol/l
4. Fasting plasma glucose greater than 6.1 mmol/l
5. Blood pressure greater than 130/85 mmol/l

Null hypothesis:
Enothelial function in patients with metabolic syndrome does not differ significantly from endothelial function in patients with only two or fewer components of metabolic syndrome or control participants. Also, angiotensin receptor blockade has no role in the reversal of endothelial dysfunction.

Hypothesis:
Angiotensin receptor blockade can reverse endothelial dysfunction in patients with metabolic syndrome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised placebo-controlled single-centre prospective study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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

Interventions
Those with metabolic syndrome (according to the definition in the hypothesis field) will be randomised to receive either valsartan 80 mg once daily or placebo using Interactive Web Response System (IWRS). A total of 120 subjects consisting of 40 normal controls and 40 patients in each treatment arm will be recruited.

Treatment duration is for 6 months. At the end of 6 months blood tests and scan measurements are repeated and compared with baseline values.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
Endothelial function. Baseline measurements and blood tests are done at study initiation and tests are repeated after 6 months and at this point primary and secondary endpoints are measured.

Secondary outcome measures
1. Carotid-intima media thickness
2. Left ventricular mass
3. Insulin resistance
4. Inflammatory markers
5. Coagulation factors

Baseline measurements and blood tests are done at study initiation and tests are repeated after 6 months and at this point primary and secondary endpoints are measured.

Overall study start date
01/01/2008

Completion date
31/12/2011

Eligibility

Key inclusion criteria
1. Individuals with metabolic syndrome without diabetes
2. Male or female at least 18 years and less than 80 years
3. Provision of signed informed consent form
4. Females of child-bearing potential (i.e., females who are not chemically or surgically sterilised or females who are not post-menopause) must have a negative urine or blood pregnancy test at enrolment and be willing to use two methods of reliable contraception, one of which must be a barrier method

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Total = 120

Key exclusion criteria
1. Prior history of overt coronary artery disease, cardiac failure, peripheral vascular disease, cerebrovascular disease or diabetes
2. History of significant renal or hepatic disease
3. Pregnant or lactating women
4. Severe hypertension (blood pressure [BP] greater than 180/110 mmHg)
5. Current antihypertensive treatment
6. Current drug therapy directly acting on the renin-angiotensin-aldosterone system
7. Chronic anaemia (haemoglobin less than 10 g/L)
8. Inadequate carotid ultrasonographic/echocardiographic images
9. Excessive alcohol consumption
10. Significant valvular disease
11. History of primary myocardial disease, e.g. dilated cardiomyopathy, viral myocarditis, hypertrophic cardiomyopathy
12. Previous enrolment or randomisation of treatment in the present study
13. Participation in another investigational drug/interventional study in the last 30 days

Date of first enrolment
01/01/2008

Date of final enrolment
31/12/2011

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Consultant Cardiologist
Manchester
United Kingdom
M13 9WL

Sponsor information

Organisation
Central Manchester and Manchester Children's Hospitals NHS Trust (UK)

Sponsor details
Research and Development
1st Floor Postgraduate Centre
Oxford Road
Manchester
England
United Kingdom
M13 9WL
+44 (0)161 276 3565
research.secretary@cmmc.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.cmmc.nhs.uk/

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Industry

Funder Name
Novartis Pharmaceuticals UK Limited (UK)

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