# 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	<ul><li>Prospectively registered</li></ul>
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	<ul><li>Record updated in last year</li></ul>

# Plain English summary of protocol

Not provided at time of registration

# **Contact information**

# Type(s)

Scientific

### Contact name

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### Contact details

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# Additional identifiers

Clinical Trials Information System (CTIS) 2006-006986-18

## Protocol serial number

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

# Study type(s)

Treatment

# 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(s)

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.

# Key secondary outcome(s))

- 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.

# 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** 

# Healthy volunteers allowed

No

# Age group

Adult

# Lower age limit

18 years

### Sex

All

# 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

United Kingdom

England

# Study participating centre Consultant Cardiologist

Manchester United Kingdom M13 9WL

# Sponsor information

# Organisation

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

# **ROR**

https://ror.org/00he80998

# Funder(s)

# Funder type

Industry

# **Funder Name**

Novartis Pharmaceuticals UK Limited (UK)

# **Results and Publications**

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?

Participant information sheet Participant information sheet 11/11/2025 11/11/2025 No Yes