

Effect of statin therapy on monocyte function in the metabolic syndrome

Submission date 13/02/2006	Recruitment status No longer recruiting	☒ Prospectively registered
		☐ Protocol
Registration date 04/04/2006	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 29/10/2012	Condition category Nutritional, Metabolic, Endocrine	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
RGHT000255

Study information

Scientific Title

Study objectives

That treatment with atorvastatin will lead to improvement in monocyte phenotype in individuals at risk of cardiovascular disease

Ethics approval required

Old ethics approval format

Ethics approval(s)

HPSS REC3, one of the Research Ethics Committees of Northern Ireland, on the 2nd August 2006 (ref: 06/NIR03/79).

Study design

Randomised double-blind placebo-controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Metabolic syndrome

Interventions

Treatment with atorvastatin 10 mg per day versus placebo.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Atorvastatin

Primary outcome(s)

Measurement of monocyte response to chemotaxins in vitro (the chemotactic index)

Key secondary outcome(s)

Measurement of expression of other molecules (e.g. cell adhesion molecules) involved in atherosclerosis in serum, monocytes and human endothelial cells exposed to patient serum

Completion date

31/07/2009

Eligibility**Key inclusion criteria**

1. Age 35 - 63 years
2. Metabolic syndrome as defined by the International Diabetes Federation, central obesity plus two of the following:
 - 2.1. Hypertension

- 2.2. Glucose intolerance
- 2.3. Low levels of high-density lipoprotein cholesterol (HDL-C)
- 2.4. Hypertriglyceridemia

Control subjects must have none of these features.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Pre-existing indication for lipid-lowering therapy, or history of intolerance of these agents
2. Use of insulin or hormone replacement therapy
3. History of liver or muscle disease
4. Impaired renal function
5. Potential for pregnancy (females)
6. Total cholesterol greater than 6.5 mmol/l or less than 4 mmol/l

Date of first enrolment

01/08/2006

Date of final enrolment

31/07/2009

Locations**Countries of recruitment**

United Kingdom

Northern Ireland

Study participating centre

Department of Clinical Biochemistry

Belfast

United Kingdom

BT12 6BA

Sponsor information

Organisation

Royal Group of Hospitals Trust (UK)

ROR

<https://ror.org/03rq50d77>

Funder(s)**Funder type**

Government

Funder Name

The Northern Ireland Research and Development Office (UK)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration