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# Effect of statin therapy on monocyte function in the metabolic syndrome

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 13/02/2006 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 04/04/2006 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 29/10/2012 | Nutritional, Metabolic, Endocrine | [ ] 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
RGHT000255

## Study information

**Scientific Title**

## Study objectives
That treatment with atorvastatin will lead to improvement in monocyte phenotype in individuals at risk of cardiovasular 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

## Secondary study design
Randomised controlled trial

## Study setting(s)
Not specified

## Study type(s)
Treatment

## Participant information sheet

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

## Secondary outcome measures

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

### Overall study start date
01/08/2006

### 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

### Age group
Adult

### Sex
Both

### Target number of participants
100

### 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**
Northern Ireland

United Kingdom

**Study participating centre**
**Department of Clinical Biochemistry**
Belfast
United Kingdom
BT12 6BA

# Sponsor information

**Organisation**
Royal Group of Hospitals Trust (UK)

**Sponsor details**
Grosvenor Road
Belfast
Northern Ireland
United Kingdom
BT12 6BA

**Sponsor type**
Hospital/treatment centre

**ROR**
https://ror.org/03rq50d77

# Funder(s)

**Funder type**
Government

**Funder Name**
The Northern Ireland Research and Development Office (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