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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

Contact name
Dr Brona Loughrey

Contact details
Department of Clinical Biochemistry
Royal Group of Hospitals Trust
Belfast
United Kingdom
BT12 6BA

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