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Assessment of the lipid lowering agents on plasma homocysteine concentration and renal function

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/09/2004	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 17/04/2015	**Condition category** Circulatory System	[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0211136321

Study information

Scientific Title
Assessment of the lipid lowering agents on plasma homocysteine concentration and renal function

Study objectives
Are the benefits of fibrate therapy offset by an increase in plasma homocysteine?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Cardiovascular: Hyperlipidemia

Interventions
3 groups:
1. Group 1 = Fibrate 1
2. Group 2 = Fibrate 2
3. Group 3 = Statin (Control)

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Lipid lowering agents

Primary outcome measure
Measurements of renal function, plasma homocysteine and lipids over an 8-month period

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/11/2003

Completion date
30/09/2005

Eligibility

Key inclusion criteria
Adult patients attending the lipid clinic with raised cholesterol and triglycerides

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/11/2003

Date of final enrolment
30/09/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Surrey County Hospital Trust
Guildford

United Kingdom
GU2 5XX

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Royal Surrey County Hospital NHS Trust (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