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Determination of whether the biological variation of fasting lipids differs between simvastatin and atorvastatin therapy in patients with type 2 diabetes: implications for treating to target

Submission date	Recruitment status
16/08/2007	No longer recruiting
Registration date	**Overall study status**
03/09/2007	Completed
Last Edited	**Condition category**
10/05/2011	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
Hull and East Yorkshire Hospital NHS Trust, Research and Development Department - R0066

Study information

Scientific Title

Acronym
SAT - Simvastatin and Atorvastatin Therapy

Study objectives
The biological variability for lipids is less after atorvastatin therapy compared to simvastatin. Therefore, to consistently achieve a target cholesterol of 5.0 mmol/L the levels will have to be reudced further with simvastatin than with atorvastatin, in orderto account for the increased variability of cholesterol found with the former.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Humber Local Research Ethics Commitee (ref: 04/Q1105/40)

Study design
Non-randomised controlled cross-over study.

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Type 2 diabetes, hypercholestrolemia

Interventions
All participants were on stable doses of medications (i.e. either atorvastatin 10 mg or simvastatin 40 mg) for at least 3 months. Biological variations of Total Cholesterol (TC), High-Density Lipoprotein Cholesterol (HDL-C), Low Density Lipoprotein Cholesterol (LDL-C), triglycerides, high sensitivity C-reactive protein (hsCRP), Vitamin D levels and oxidative stress markers were assessed by measuring 12-hour fasting blood samples at four-day intervals on 10 consecutive occasions. Thereafter the patients on simvastatin were changed to atorvastatin 10

mg and vice versa. After 3 months, the biological variation of lipid parameters, hsCRP, Vitamin D levels and oxidative stress markers were assessed again by measuring fasting blood samples at four-day intervals on 10 consecutive occasions in these patients.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
simvastatin , atorvastatin

Primary outcome measure
Biological variability of TC and LDL-C (see Interventions for timepoints of measurement).

Secondary outcome measures
Biological variation of triglycerides and hsCRP (see Interventions for timepoints of measurement).

Overall study start date
01/02/2005

Completion date
01/02/2007

Eligibility

Key inclusion criteria
Type 2 diabetes on either atorvastatin 10 mg or simvastatin 40 mg.

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Not on concomitant fibrate or additional lipid lowering therapy
2. Inadequately treated hypothyroidism
3. Nephrotic syndrome

Date of first enrolment
01/02/2005

Date of final enrolment
01/02/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Michael White Diabetes Centre
Hull
United Kingdom
HU3 2JZ

Sponsor information

Organisation
Hull and East Yorkshire Hospitals NHS trust (UK)

Sponsor details
c/o Mrs Nina Dunham
Research and Development Manager
Castle Hill Hospital
Castle Road
Cottingham
East Yorkshire
Hull
England
United Kingdom
HU16 5JQ

Sponsor type
Hospital/treatment centre

Website
http://www.hey.nhs.uk/

ROR
https://ror.org/01b11x021

Funder(s)

Funder type
University/education

Funder Name
University of Hull (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2008		Yes	No