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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	[_] Prospectively registered
16/08/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/09/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/05/2011	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Stephen Atkin

Contact details
Michael White Diabetes Centre
Hull Royal Infirmary
220-236 Analby Road
Hull
United Kingdom
HU3 2JZ

Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s)
Biological variation of triglycerides and hsCRP (see Interventions for timepoints of measurement).

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

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
United Kingdom

England

Study participating centre
Michael White Diabetes Centre
Hull

United Kingdom
HU3 2JZ

Sponsor information

Organisation
Hull and East Yorkshire Hospitals NHS trust (UK)

ROR
https://ror.org/01b11x021

Funder(s)

Funder type
University/education

Funder Name
University of Hull (UK)

Results and Publications

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