

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

16/08/2007

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

03/09/2007

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

10/05/2011

Condition category

Nutritional, Metabolic, Endocrine

☐ Individual participant data

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

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 reduced further with simvastatin than with atorvastatin, in order to 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 Committee (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, hypercholesterolemia

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