

The effect of statin treatment on mitochondrial function and lipid oxidation

Submission date 28/02/2018	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 21/03/2018	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 24/01/2020	Condition category Nutritional, Metabolic, Endocrine	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Hypercholesterolemia (high cholesterol) is a major risk factor for development of stroke and coronary heart disease. Statins are tablets that lower cholesterol and are the first choice of treatment for high cholesterol; around 10% of the population in the Nordic countries (Denmark, Sweden and Norway) are using statins. However, skeletal muscle pain (myalgia) is reported in up to 30% of patients, ranging from mild pain to rare cases of severe pain and complications in conditions such as rhabdomyolysis. The mechanisms behind the muscle pain are not known, but mitochondrial function (production of energy in cells) could be involved. Furthermore it is not known if lipid oxidation is impaired in patients taking simvastatin.

This study aims to determine if simvastatin treatment is affecting mitochondrial function as well as lipid oxidation.

Who can participate?

1. Males aged 30 – 60 years
2. Males aged 30 – 60 years taking simvastatin for at least 1 year

What does the study involve?

Participants attend the laboratory on two occasions, both following a period of fasting. At the first visit, they have

What are the possible benefits and risks of participating?

Participants will benefit from gaining knowledge of their own clinical parameters such as body composition, glucose homeostasis and cardiorespiratory fitness.

All participants have a muscle sample taken and an oral glucose tolerance test, which are both invasive procedures with a small risk of infection.

Where is the study run from?

University of Copenhagen Xlab (Denmark)

When is the study starting and how long is it expected to run for?

October 2009 – December 2012

Who is funding the study?

1. Danish Council for Independent research-Medical Sciences (Denmark)
2. Nordea Foundation (Denmark)

Who is the main contact?

Mr Steen Larsen (Scientific)

Contact information

Type(s)

Scientific

Contact name

Mr Steen Larsen

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Additional identifiers

Protocol serial number

H-4-2009-095

Study information

Scientific Title

Is mitochondrial function and lipid oxidation impaired in patients treated with simvastatin compared with well matched controls?

Study objectives

Mitochondrial function and lipid oxidation is impaired with simvastatin treatment

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethical committee of Denmark, 09/09/2009, ref: H-4-2009-095

Primary study design

Observational

Study design

Observational cross-sectional study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Mitochondrial function and lipid oxidation

Interventions

The study is a cross-sectional study, so there was no intervention. 10 healthy volunteers are recruited, and 10 participants taking simvastatin. Participants are matched for age, activity level, maximal oxygen uptake and obesity because it is known that all these factors influence mitochondrial function and lipid oxidation.

All participants come to the laboratory for a screening visit having fasted, at which medical history, blood pressure and body composition are recorded. A resting electrocardiogram, oral glucose tolerance test and maximal oxygen consumption test are also performed.

Participants return for an experimental day, again following fasting, where they have a blood sample taken, resting metabolic rate measured, a muscle biopsy, maximal fat oxidation test and maximal oxygen test.

Intervention Type

Not Specified

Primary outcome(s)

Mitochondrial function measured by high-resolution respirometry and lipid oxidation (whole body lipid oxidation) and protein analysis at the second visit.

Key secondary outcome(s)

Glucose homeostasis measured using the oral glucose tolerance test at the first visit.

Completion date

31/12/2012

Eligibility

Key inclusion criteria

Simvastatin group

1. Male participants aged 30-60 years
2. Normal kidney and liver function
3. BMI between 25-35
4. Taking simvastatin for at least 1 year
5. Does not have type II Diabetes

Control group

1. Male participants aged 30-60 years
2. Normal kidney and liver function
3. BMI between 25-35
4. Does not have type II Diabetes

Participant type(s)

Mixed

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

Total final enrolment

20

Key exclusion criteria

1. Must not be taking medication (other than simvastatin).
2. Must not be disposed to type 2 diabetes

Date of first enrolment

01/01/2010

Date of final enrolment

31/05/2012

Locations**Countries of recruitment**

Denmark

Study participating centre

Xlab

University of Copenhagen

Panum

Blegdamsvej 3b

Copenhagen N

Denmark

2200

Sponsor information**Organisation**

University of Copenhagen

ROR

<https://ror.org/035b05819>

Funder(s)

Funder type

Research council

Funder Name

The Danish Council for Independent Research-Medical Sciences

Funder Name

Nordea Foundation

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository on a secure network drive at the University of Copenhagen. All subjects have a number, so that data is completely anonymised.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	12/09/2018	24/01/2020	Yes	No