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The effect of statin treatment on mitochondrial function and lipid oxidation

Submission date
28/02/2018

Recruitment status
No longer recruiting

Registration date
21/03/2018

Overall study status
Completed

Last Edited
24/01/2020

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Observational cross-sectional study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

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

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

Overall study start date
01/10/2009

Completion date
31/12/2012

Eligibility

Key inclusion criteria
Simvastin 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

Age group
Adult

Sex
Male

Target number of participants
20 subjects; 10 in the simvastatin treated group and 10 in the control group.

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

Sponsor details
Xlab
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Sponsor type
University/education

Website
http://www.ku.dk/english/

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

Publication and dissemination plan
The data will be published in relevant international peer reviewed journals.

Intention to publish date
31/12/2018

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