# The effects of cholesterol-lowering medication on exercise performance.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

# **Summary**

## ID

NL-OMON28167

**Source** Nationaal Trial Register

Brief title STATEX

## **Health condition**

Adopting or maintaining a physically active lifestyle is often not feasible for statin users, as muscle toxicity is the most frequent adverse effect of statins. In multiple studies it is suggested that muscle mitochondria are affected in statin users with muscle complaints. However, it is currently unknown if the exercise intolerance of statin users with muscle complaints is causally related to disturbances in muscle mitochondrial function.

Key words: statins, physically active lifestyle, exercise intolerance, muscle toxicity, mitochondrial function.

Kernwoorden: statines, fysiek actieve leefstijl, inspanningsintolerantie, spierklachten, mitochondriale functie.

## **Sponsors and support**

Primary sponsor: Department of Physiology, Radboudumc Source(s) of monetary or material Support: Department of Physiology, Radboudumc

## Intervention

## **Outcome measures**

#### **Primary outcome**

- Exercise-induced change in aerobic fitness
- Exercise-induced change in mitochondrial mass and function and substrate use

#### Secondary outcome

- Exercise-induced change in muscle strength, contractile function and fatigue, and muscle mass

- Exercise-induced change in pain- and fatigue rating, and quality of life

# **Study description**

### **Study objective**

We hypothesize that improving both the quantity and quality of the mitochondria by exercise training may counteract the statin-induced myocellular changes, and optimize muscle function and overall exercise capacity.

#### Study design

All measurements are performed before exercise training and after 12 weeks of exercise training.

#### Intervention

Combined endurance and resistance training program

# Contacts

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# **Eligibility criteria**

# **Inclusion criteria**

- 3 study groups:
- 1. Statin users with self-reported muscle symptoms
- 2. Statin users without muscle symptoms or other side effects
- 3. A control group, not using any statins

#### Inclusion criteria

- Males and females aged 40 to 70 years.
- Mentally able to give informed consent.
- Current statin user (group 1-2) for at least 3 months

## **Exclusion criteria**

- Familial hypercholesterolemia
- History of cardiovascular event within 1 year of study participation
- Known hereditary muscle defect
- Known mitochondrial disease
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# Study design

## Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

## Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	17-04-2017
Enrollment:	72
Туре:	Anticipated

# **Ethics review**

Not applicable Application type: Not applicable

# **Study registrations**

## Followed up by the following (possibly more current) registration

No registrations found.

# Other (possibly less up-to-date) registrations in this register

No registrations found.

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# In other registers

Register	ID
NTR-new	NL5972
NTR-old	NTR6346
Other	NL59192.091.16 : 2016-2867

# **Study results**