Discontinuing Statins in Multimorbid Older Adults without Cardiovascular Disease (STREAM) - a randomized non-inferiority clinical trial

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The primary objective is to compare a composite endpoint of major CV events and all-cause death between control and intervention group.Secondary objectives are the comparison of patient-centered outcomes between the two groups.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON53293

Source
ToetsingOnline

Brief title
STREAM

Condition

- Coronary artery disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Cardiovascular disease

Research involving
Human

Sponsors and support

Primary sponsor: University Hospital Bern (Inselspital)
Source(s) of monetary or material Support: Swiss National Science Foundation

Intervention

Keyword: Discontinuing, Older adults, RCT, Statins

Outcome measures

Primary outcome

The primary endpoint is a composite endpoint of major CV events (non-fatal myocardial infarction, non-fatal ischemic stroke) and all-cause death over a follow-up period of 2 years.

Secondary outcome

Secondary endpoints are all-cause death, non-CV death, major CV events, coronary and peripheral artery revascularization, EQ-5D questionnaire, verbal numeric pain rating score, falls, SARC-F questionnaire and Girerd Medication adherence scale.

Study description

Background summary

Statins are among the most widely used drugs. While they were found to be effective for primary and secondary prevention of cardiovascular disease (CVD) in middle-aged subjects, their benefits for primary prevention in older people (aged >=70) without CVD are uncertain, particularly for those with multimorbidity. However, statin side effects and drug interactions are common in a multimorbid elderly population and can negatively impact quality of life and increase adverse drug reaction-related hospitalizations. Therefore, we aim to conduct a statin deprescribing randomized controlled trial (RCT) to provide guidance on the long-term benefits and risks for the ever-growing multimorbid elderly population.

Study objective

The primary objective is to compare a composite endpoint of major CV events and all-cause death between control and intervention group.
Secondary objectives are the comparison of patient-centered outcomes between the two groups.

Study design

The study is a multicenter, randomized, non-inferiority trial. The study is open-labelled, with blinded outcome adjudication. Study subjects are randomly assigned in a 1:1 ratio to either discontinue (intervention arm) or continue (control arm) statin therapy.

Intervention

In the intervention group, statin therapy will be stopped

Study burden and risks

Potential risks of discontinuing statins might include increased CV events. However, current trials found no benefits of statins after 70 years of age for primary prevention. In the multimorbid elderly, statin side effects and drug interactions are common and discontinuing statin might positively impact quality of life.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

• >=70 years of age
• Multimorbid withh >=2 coexistent chronic conditions (defined by ICD-10 codes) with an estimated duration of 6 months or more based on clinical decision, besides dyslipidemia treated by statins
• Taking a statin for >=80% of the time during the year before baseline

Exclusion criteria

• Secondary prevention based on previous large statin trials (History of cardiovascular disease)
• Aortic disease that required a vascular repair or aortic aneurysm
• Diagnosis of familial hypercholesterolemia
• Elevated risk of death within 3 months after baseline
• Participation to a clinical trial with potential impact on the STREAM cardiovascular endpoints

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-07-2023
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	08-05-2023
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	23-10-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	12-01-2024
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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.

In other registers

Register	ID
ClinicalTrials.gov	NCT05178420
CCMO	NL83907.058.23