

How using carotid artery ultrasounds affects taking cholesterol medications

Submission date 17/06/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/07/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/08/2025	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Cardiovascular diseases are the leading cause of death in Western society in the 21st century. Therefore, it is crucial to identify risk factors early to prevent serious health problems. To assess cardiovascular risk in seemingly healthy individuals, established tools like the Framingham and SCORE2 tables are used. These tools rely on measurements of blood pressure, cholesterol levels, and basic patient information. However, recent research suggests that additional tests can provide more valuable information for making treatment decisions and assessing individual risk.

One important test is carotid artery ultrasonography, which uses ultrasound to detect the presence of atherosclerotic plaques. These plaques are fatty deposits in the arteries that can lead to serious cardiovascular issues. Identifying these plaques early can prompt immediate prevention measures.

Convincing healthy individuals with risk factors, but no symptoms, to take medication can be difficult because they might be concerned about side effects, even though these side effects are usually very minor. As a result, less than half of these people stick to their medication regimen for preventing cardiovascular problems.

Carotid artery ultrasonography can show patients the actual plaques in their arteries on the ultrasound screen. This visual evidence can clearly demonstrate that their cardiovascular health is not as good as they might think. We believe that seeing these plaques will significantly improve their willingness to take lipid-lowering medications. Additionally, knowing about the plaques can motivate both patients and doctors to be more proactive in ensuring medication adherence.

The aim of our study is to evaluate whether performing carotid artery ultrasonography affects how well seemingly healthy individuals with cardiovascular risk factors stick to their lipid-lowering medication regimen.

Who can participate?

The study focuses on individuals aged 40 to 69 years who have been evaluated as having a high

or very high risk of cardiovascular disease (CVD) and have no prior history of using antilipemic drugs.

What does the study involve?

The study involves 3 visits to family medicine practitioners, POCUS of carotid arteries (examination) and taking 3 blood samples upon visits.

What are the possible benefits and risks of participating?

There are no risks. A main benefit is free ultrasonographic exam of carotid arteries.

Where is the study run from?

KRKA, tovarna zdravil, d.d., Novo Mesto (Slovenia)

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

January 2023 to December 2024

Who is funding the study?

Medicinska fakulteta, Univerza v Ljubljani (Slovenia)

Who is the main contact?

Anej Kebrič, anej.kebric@gmail.com

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

01102021

Study information

Scientific Title

Effect of use of carotid artery point-of-care ultrasonography on lipid lowering drug adherence

Study objectives

The average normalized difference between initial and target LDL cholesterol levels will be greater in the intervention group compared to the control group at the end of the observation period.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 03/01/2023, Komisija republike Slovenije za medicinsko etiko (Stefanova ulica 5, Ljubljana, 1000, Slovenia; +386 14786906; kme.mz@gov.si), ref: 0120-469/2022/3

Study design

Interventional randomized controlled trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Low statin adherence in apparently healthy individuals with high and very high CVD risk.

Interventions

Patients meeting the inclusion criteria and signing the informed consent form will be randomized within each clinic (randomization performed by the e-CRF program). In the intervention group, carotid artery POCUS will be performed at the first visit, recording short video clips of their carotid arteries. These recordings will be shown to participants, explaining what they see (some will see their atherosclerotic plaques, others a healthy vessel wall). In the control group, participants will receive standard care according to guidelines, without carotid artery POCUS. All participants in the intervention group with visible atherosclerotic plaques will receive personalized prevention measures in addition to guideline-recommended statin therapy.

Follow-Up: During the observation period (9 months), the control group will receive standard care with 4 visits (at 3-month intervals) to measure LDL cholesterol levels. In the intervention group, carotid artery POCUS will be performed only at the first visit, with the same follow-up protocol for LDL cholesterol levels as the control group.

Participants will be randomized within each clinic, divided into two unequal parts (2:1). The larger group will be the intervention group, and the smaller group will be the control group. Each clinic will include 9 to 50 (or more) participants, depending on its capacity. Randomization will be performed by e-CRF program.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Fasting blood LDL cholesterol levels will be measured using blood test before intervention and 9 months after intervention.

Key secondary outcome(s)

1. Prevalence of atherosclerotic plaques in the carotid arteries of apparently healthy individuals with risk factors measured using ultrasonographic recording at baseline for intervention group, at 9 months for controlled group
2. Sensitivity and specificity of identifying atherosclerotic plaques using carotid artery POCUS performed by family medicine physicians measured using ultrasonographic recording at baseline for intervention group, at 9 months for controlled group
3. Assess how the presence of atherosclerotic plaques visible to the patient affects adherence to lipid-lowering medications measured using difference in LDL cholesterol levels at baseline and in 9 months time
4. Determine how the presence of atherosclerotic plaques identified by the physician influences the intensity of the prescribed therapy measured by observing doses of prescribed medications at 6 months

Completion date

31/12/2024

Eligibility

Key inclusion criteria

1. Aged 40 to 69 years
2. CVD risk evaluated as high or very high
3. No prior use of antilipemic drugs

Participant type(s)

Healthy volunteer, Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

40 years

Upper age limit

69 years

Sex

All

Total final enrolment

380

Key exclusion criteria

1. Diabetes mellitus type 1 or type 2
2. Carotid ultrasound conducted in the past 5 years
3. Chronic kidney disease
4. Previously known cvd

5. Family hypercholesterolemia
6. Active malignant disease
7. "Difficult to manage" psychiatric disorder
8. Language barrier (subject's knowledge of slovene language is inadequate for appropriate communication with physician)
9. Estimated life expectancy of less than 1 year.

Date of first enrolment

01/03/2023

Date of final enrolment

31/03/2024

Locations

Countries of recruitment

Slovenia

Study participating centre

Ambulanta Jerković d.o.o and Ambulanta Šaško

Osojnikova 9

Ptuj

Slovenia

2250

Study participating centre

Dentiko d.o.o.

Pekerska cesta 56

Maribor

Slovenia

2000

Study participating centre

ZD Ljubljana (Rudnik, Šentvid, Vič)

Rakovniška ulica 4,

Ob zdravstvenem domu 1,

Šestova ulica 10,

Ljubljana

Slovenia

1000

Study participating centre

ZD Ptuj
Mladinska ulica 9
Kidričevo
Slovenia
2325

Study participating centre

Arcus Medici
Trg svobode 9
Žiri
Slovenia
4226

Study participating centre

Medicinski center KRKA d.o.o.
Šmarješka cesta 4
Novo Mesto
Slovenia
8000

Study participating centre

ZD Vrhnika
Cesta 6. Maja 11
Vrhnika
Slovenia
1360

Study participating centre

Lantana d.o.o.
Partizanska pot 8a
Litija
Slovenia
1270

Sponsor information

Organisation

KRKA, tovarna zdravil, d.d., Novo Mesto

Funder(s)

Funder type

University/education

Funder Name

Medicinska fakulteta, Univerza v Ljubljani

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-publicly available repository (Electronic Case Report Form - eCRF)

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		05/08/2025	07/08/2025	Yes	No