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How using carotid artery ultrasounds affects taking cholesterol medications

Submission date
17/06/2024

Recruitment status
No longer recruiting

Registration date
26/07/2024

Overall study status
Completed

Last Edited
07/08/2025

Condition category
Circulatory System

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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

Participant information sheet
Not avaliable in web format, please use contact details to request a participant information sheet.

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

Secondary outcome measures
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

Overall study start date
03/01/2023

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

Age group
Adult

Lower age limit

40 Years

Upper age limit
69 Years

Sex
Both

Target number of participants
500

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

Sponsor details
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Sponsor type
Industry

Website
https://www.krka.si/

Funder(s)

Funder type
University/education

Funder Name
Medicinska fakulteta, Univerza v Ljubljani

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal.

Intention to publish date

01/12/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publicly avaliable 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