Reviving Early Diagnosis of Cardiovascular Disease in the Utrecht Health Project

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RED-LRGP: To investigate the yield of a screen-like early diagnosis strategy as compared to usual primary care in terms of the number of newly diagnosed coronary artery disease, atrial fibrillation, and heart failure in community people aged 50-80...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON56354

Source
ToetsingOnline

Brief title
RED-UHP

Condition

- Other condition
- Cardiac arrhythmias

Synonym
1) atrial fibrillation, 2) coronary artery disease, 3) heart failure

Health condition

hartaandoeningen: kransslagaderaandoeningen, falen van de hartfunctie

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: OMRON Healthcare Europe B.V.

Intervention

Keyword: - cardiovascular diseases, - cohort study, - early diagnosis, - primary health care

Outcome measures

Primary outcome

RED-LRGP:

The primary outcomes are newly detected CAD, AF and HF after one year

follow-up.

Secondary outcome

RED-LRGP:

- Health-related quality of life

- Cost-effectivity

Night-LRGP:

The primary outcome is the user-friendliness and usability of the Omron

NightView as compared to the ABPM notably for measurements at night.

Study description

Background summary

There is a need for a proactive strategy for early detection of chronic progressive cardiovascular diseases, notably those in the cardiac *continuum* namely coronary artery disease (CAD), atrial fibrillation (AF), and heart failure (HF). By early detection and management of CAD, AF and HF, acute events, e.g. acute myocardial infarction, stroke, or acute heart failure, may

be prevented and further deterioration of disease prevented or postponed. So far, such an early detection strategy in the open adult population is lacking.

Study objective

RED-LRGP:
To investigate the yield of a screen-like early diagnosis strategy as compared to usual primary care in terms of the number of newly diagnosed coronary artery disease, atrial fibrillation, and heart failure in community people aged 50-80 years.

Night-LRGP:
To investigate the user-friendliness and usability of the Omron NightView device as compared to a conventional ABPM device for blood pressure measurements notably at night.

Study design

RED-LRGP:
A diagnostic randomized trial comparing the full, screen-like early diagnosis strategy to usual care.

Night-LRGP:
A cross-over trial on the user-friendliness and usability of the Omron NightView vs. conventional 24 hours ABPM.

Intervention

RED-LRGP:
Participants will be randomized to 1) the intervention group (early diagnosis strategy), or 2) control group (usual primary care)
1) Participants in the intervention group will fill out the 'early diagnosis questionnaire' and additional questionnaires. In addition, they will undergo a physical examination, electrocardiography, and echocardiography. Blood samples will also be drawn and a spot urine sample will be collected.
2) Participants in the control group will receive usual primary care. No measurements will be performed.

Night-LRGP:
Participants undergo blood pressure measurements at home with the NightView device and a regular ABPM.

Study burden and risks

The burden associated with participation in the RED-LRGP study will be relatively low as only two extra visits will be required. Participants will be

asked to fill out questionnaires and those randomized to the intervention arm will also undergo a physical examination, electrocardiography, echocardiography, and laboratory testing. The RED-LRGP study is a low-risk study, as all are established non-invasive and minimally invasive (blood taking) diagnostic tests. The results of the investigations in the study will be shared with the treating general practitioner to help him/her make management choices. There is a potential benefit associated with participation, since we aim to uncover early stages of CVD that might have not been detected otherwise, and for which early treatment options are available.

The burden associated with participation in the Night-LRGP study will also be relatively low, as only two extra visits are required. Participants will be asked to fill out questionnaires and blood pressure will be measured at home over several days and nights. This can potentially lead to a reduction in sleep quality. There is a potential benefit associated with participation, as high blood pressure can be detected and treated early, or treatment for high blood pressure can be adjusted.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

RED-LRGP:
- Being a participant of Utrecht Health Project (UHP; in Dutch: Leidsche Rijn Gezondheidsproject (LRGP)) and registered with a general practitioner at the Leidsche Rijn Julius Health Care foundation (in Dutch: Leidsche Rijn Julius Gezondheidcentra).
- Having indicated in the LRGP informed consent to be interested in participating in further research.
- Aged 50-80 years.

Night-LRGP:
- Being a participant of the RED-LRGP study and enrolled in the intervention arm.
- Willing to undergo multiple ambulatory day and multiple night BP measurements with the Omron NightView and a conventional BP measurement device and to fill out questionnaires on user-friendliness and quality of sleep.

Exclusion criteria

RED-LRGP:
- Diagnosed with coronary artery disease and heart failure and atrial fibrillation.
- Undergoing major (cardiovascular) surgery, and/or revascularisation therapy and/or transplantation treatment within 3 months after enrolment.
- Not willing to give written informed consent for RED-LRGP.
- Not allowing incidental findings to be reported to him/herself or their own general practitioner.

Night-LRGP:
- Known with permanent atrial fibrillation; this hampers automatic blood pressure measurements.
- Not willing or able to give informed consent for Night-LRGP.

Study design

Design

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

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2023
Enrollment:	1464
Type:	Actual

Medical products/devices used

Generic name:	NightView (Omron HEM-9601T-E3)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	19-05-2023
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	15-11-2023
Application type:	Amendment
Review commission:	METC NedMec

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	NCT05775354
CCMO	NL82944.041.23