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Secondary preventive, nurse based, telephone follow-up for reduction of cardiovascular events after acute coronary syndrome or stroke

Submission date	Recruitment status	[_] Prospectively registered
04/12/2014	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/01/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/11/2024	Circulatory System	

Plain English summary of protocol

Background and study aims
A substantial proportion of mortality, morbidity and disability rates in Sweden and internationally is due to myocardial infarctions and strokes. Effective treatments to avoid another event or death are available but the use of these treatments in routine care needs to be improved. The aim of this study is to see whether long-term follow-ups after a myocardial infarction or stroke by specially trained cardiovascular nurses (treatment group) provide a better use of preventive treatment compared to routine follow-ups in primary care (control group) and whether the risk of death or another myocardial infarction or stroke decrease?

Who can participate?
All patients diagnosed with a myocardial infarction or stroke over a period of approximately five years in the county of Jämtland, treated at the county's only hospital, Östersund Hospital (Sweden).

What does the study involve?
In the treatment group the goal is to rapidly reach and then maintain set treatment targets for blood pressure and blood lipids. Patients in the control group will receive today's standard of care as usual given by their general practitioner.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
The study is run from Östersund Hospital. Östersund Hospital is the only hospital in the county of Jämtland, Sweden. All patients will be recruited from the county of Jämtland.

When is the study starting and how long is it expected to run for?
January 2010 to December 2017

Who is funding the study?
The study is funded by The Research and Development Unit at Jamtland County Council (Sweden).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Secondary preventive, nurse based, telephone follow-up for reduction of cardiovascular events after acute coronary syndrome or stroke: a randomised, controlled, population based study

Acronym
NAILED CV (Nurse based, Age independent Intervention to Limit Evolution of Disease after CardioVascular events)

Study objectives
We hypothesised that the NAILED CV (Nurse based, Age independent Intervention to Limit Evolution of Disease after CardioVascular events) Outcome trial would reduce cardiovascular events more effectively than usual care

Ethics approval required
Old ethics approval format

Ethics approval(s)

The Regional Ethical Review Board, Umeå University, Umeå, Sweden approved on 16/12/2009, ref: Dnr 09-142M, and 10/06/2013, ref: Dnr 13-204-32M

Study design
Single-centre randomized open controlled trial with two parallel groups

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Acute coronary syndrome, stroke and transient ischemic attack

Interventions
A study nurse will contact patients randomised to the intervention group by phone 1 month after discharge. Before the call a blood sample for lipids will be taken and a standardised blood pressure control will be performed. Blood pressure will be measured after 5 minutes in the sitting position and after 1 minute standing. The tests will be performed by a district nurse, or, for patients in the intervention group living close to the hospital, by a study nurse. Self reported compliance with medication, tobacco use and physical activity will be recorded. During the call the patient will be informed about the test results and if a change in medication is necessary. Tobacco use, physical activity and dietary habits will be discussed. Smoking cessation will be supported. Physical activity of moderate intensity 30 minutes or more most days of the week will be encouraged but also adjusted to the individual patients capacity. Dietary advice to reduce saturated fat and increase the intake of fruit and vegetables will be given. If the patients cholesterol or blood pressure values are above target medication will be adjusted after contact with a study physician. Repeat tests will be taken within approximately 4 weeks and further adjustments made if necessary until target values are reached or no further changes are reasonable. The same routine will be applied after 12 months and thereafter early. The target values are: blood pressure <140 / <90 mmHg (optionally <140 / <85 mmHg in diabetic patients), total cholesterol < 4.5 mmol/l, and low density lipoprotein (LDL) < 2.5 mmol/l (<1.8 in diabetic subjects) to comply with local guidelines.

Patients randomised to the usual care group will also be contacted by phone 1 month after discharge after blood pressure and lipid profile measurements. Self reported compliance, tobacco use and physical activity will be recorded. Their general practitioner who receives the test results (lipid profile and blood pressure) will provide all medical care and no additional intervention will be given as a result of participation in the study. The same routine will be applied after 12 months and thereafter yearly.

Intervention Type
Other

Primary outcome(s)
Major adverse cardiovascular events identified at the end of trial by reviewing patients medical records and by the Swedish National Patient Register and the Swedish Cause of Death Register defined as:

1. Non-fatal major coronary event: myocardial infarction or coronary revascularisation
2. Non-fatal stroke
3. Cardiovascular death

Key secondary outcome(s))
Major adverse cardiovascular events identified at the end of trial by reviewing patients medical records and by the Swedish National Patient Register and the Swedish Cause of Death Register.
1. Separate assessment of the individual components of the primary endpoint
2. Transient ischemic attack
3. All-cause mortality
4. Separate assessment of the acute coronary syndrome and the stroke / TIA cohorts

Completion date
06/04/2020

Eligibility

Key inclusion criteria
1. All patients living in the county of Jämtland, Sweden, and hospitalised with a diagnosis of an acute coronary syndrome (ACS, acute myocardial infarction or unstable angina pectoris), stroke (ischemic or hemorrhagic) or transient ischemic attack (TIA) will be assessed for inclusion
1.1. Östersund hospital is the only hospital in the county and all patients, terminal care excluded, with symptoms of an ACS or suspected stroke or TIA are referred for diagnostic evaluation. A routine for identification of all patients in the hospital with a possible ACS or stroke/TIA has been established in previous studies.
2. All patients with a physical and mental capacity to communicate by telephone

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
1833

Key exclusion criteria
1. Patients with severe disease
2. Aphasia
3. Dementia
4. Deafness
5. Participation in another trial

Date of first enrolment

01/01/2010

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
Sweden

Study participating centre
Cardiology, Dept. of Public Health and Clinical Medicine Umea University
Östersund
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Sponsor information

Organisation
Jamtland County Council (Sweden)

Funder(s)

Funder type
Government

Funder Name
The Research and Development Unit, Jamtland County Council (Sweden)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article		02/08/2021	08/02/2023	Yes	No
Other publications		11/11/2024	20/11/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes