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Secondary preventive, nurse based, telephone follow-up for risk factor control after an acute coronary syndrome

Submission date
10/07/2011

Recruitment status
No longer recruiting

Registration date
24/08/2011

Overall study status
Completed

Last Edited
20/11/2024

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Myocardial infarction (heart attack) is a common cause of death and disability in Sweden and internationally. There are a number of effective treatments to keep a person healthy after an infarction but the use of these in routine care has not been successful. The aim of this study is to find out whether long-term follow-ups after a myocardial infarction by specially trained nurses improve the use of effective preventive treatments, and improve blood pressure, lipid values, exercise habits and smoking cessation.

Who can participate?
All patients diagnosed with a myocardial infarction over a period of about three years in the county of Jämtland, Sweden, who were treated at the county's only hospital, Östersund Hospital.

What does the study involve?
You will be randomly allocated to one of two groups: the intervention group or the usual care group. Patients in both groups will provide a blood sample and a blood pressure measurement, and your cardiac symptoms, compliance with medication, tobacco use and physical activity will be recorded. Both groups will be contacted by a study nurse by phone 1 month after discharge. If you are allocated to the intervention group, during the call you will be informed about the test results and if a change in medication is necessary. The study nurse will support smoking cessation, encourage physical activity, and provide dietary advice to reduce saturated fat and increase your intake of fruit and vegetables. If your cholesterol or blood pressure values are high your medication will be adjusted after contact with a study physician. Repeat tests will be taken within about 4 weeks and further adjustments made if necessary. The same routine will be applied after 12, 24 and 36 months. Patients allocated to the usual care group will also be contacted by phone 1 month after discharge. All medical care will be given by their general practitioner who receives the test results and no additional intervention will be given as a result of participation in the study. The same routine will be applied after 12, 24 and 36 months.

What are the possible benefits and risks of participating?
Potentially participants can get a more effective preventive treatment. Only standard medical treatments for hypertension and lipid lowering are used.

Where is the study run from?
Dept. of Public Health and Clinical Medicine Umea University (Sweden)

When is the study starting and how long is it expected to run for?
January 2010 to December 2012

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

Who is the main contact?
Ass prof Thomas Mooe
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Secondary preventive, nurse-based, telephone follow-up for risk factor control after an acute coronary syndrome: a randomised, controlled, population-based study

Acronym
NAILED ACS

Study objectives
The NAILED ACS risk factor trial (Nurse based, Age independent Intervention to Limit Evolution of Disease after Acute Coronary Syndrome). We hypothesised that this nurse based, telephone follow-up would reduce risk factor levels more effectively than usual care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Regional Ethical Review Board, Umeå University, Umeå, Sweden, 16/12/2009, ref: Dnr 09-142M

Study design
Single-centre randomised controlled trial with two parallel groups

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Acute coronary syndrome

Interventions
Patients randomised to the intervention group will be contacted by a study nurse 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. Cardiac symptoms, 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 by

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, 24 and 36 months. The target values are: systolic blood pressure <140 / <90 mmHg (optionally <130 / <80 mmHg in patients assessed to be at high risk i.e. diabetics), total cholesterol < 4.5 mmol/l, LDL < 2.5 mmol/l.

Patients randomised to the usual care group will also be contacted by phone 1 month after discharge after blood pressure and lipid profile measurements. Cardiac symptoms, self reported compliance, tobacco use and physical activity will be recorded. All medical care will be given by their general practitioner who receives the test results (lipid profile and blood pressure) and no additional intervention will be given as a result of participation in the study. The same routine will be applied after 12, 24 and 36 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Total cholesterol and low density lipoprotein (LDL) cholesterol
2. Sitting systolic and diastolic blood pressure
An adjusted analysis to account for differences in important baseline variables, if any, will be performed. Outcomes are measured after 12, 24 and 36 months of follow-up.

Secondary outcome measures
1. The proportion of patients reaching the target for:
1.1. Total cholesterol and LDL cholesterol
1.2. Sitting systolic and diastolic blood pressure
1.3. Standing systolic and diastolic blood pressure
1.4. Smoking rates
1.5. Change in body mass index and physical activity
Blood pressures are measured standardised as described above. Smoking (yes/no) and physical activity (duration and intensity/week) are self reported. Subanalyses according to age and gender are planned.

Overall study start date
01/01/2010

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1. All patients living in the county of Jämtland, Sweden, and hospitalised with a diagnosis of myocardial infarction or unstable angina 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 a suspected acute coronary syndrome are referred for diagnostic evaluation.

A routine for identification of all patients in the hospital with a possible acute coronary syndrome (ACS) has been established in previous studies.
2. All patients with a physical and mental capacity to communicate by telephone

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
800

Total final enrolment
962

Key exclusion criteria
1. Patients with severe disease
2. Not able to communicate by telephone
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
Dept. of Public Health and Clinical Medicine Umea University
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Sponsor information

Organisation
Jamtland County Council (Sweden)

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Sponsor type
Research council

Funder(s)

Funder type
Research council

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	15/08/2014		Yes	No
Results article	results	14/10/2015		Yes	No
Results article	results	15/02/2016		Yes	No
Results article	results	30/04/2016		Yes	No

Results article	Substudy results	06/09/2021	08/09/2021	Yes	No
Other publications		11/11/2024	20/11/2024	Yes	No