

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

<b>Submission date</b> 10/07/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 24/08/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 20/11/2024	<b>Condition category</b> Circulatory System	<input type="checkbox"/> 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

thomas.mooe@medicin.umu.se

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Thomas Mooe

**Contact details**

Dept. of Public Health and Clinical Medicine Umea University

Hus 10 Plan 5

Östersund

Sweden

SE-83183

-

thomas.mooe@medicin.umu.se

## 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

Östersund

Sweden

SE-83183

**Sponsor information**

## Organisation

Jamtland County Council (Sweden)

## Sponsor details

The Research and Development Unit

Jamtland County Council

Box 654

Östersund

Sweden

SE-83127

-

jamtlands.lans.landsting@jll.se

## 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?
<a href="#">Protocol article</a>	protocol	15/08/2014		Yes	No
<a href="#">Results article</a>	results	14/10/2015		Yes	No
<a href="#">Results article</a>	results	15/02/2016		Yes	No
<a href="#">Results article</a>	results	30/04/2016		Yes	No

<a href="#">Results article</a>		06/09/2021	08/09/2021	Yes	No
<a href="#">Other publications</a>	Substudy results	11/11/2024	20/11/2024	Yes	No