

Secondary preventive, nurse-based, telephone follow-up for risk factor control after stroke or transient ischemic attack

Submission date 13/05/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 19/06/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 20/11/2024	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Stroke 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 a stroke. Low blood pressure, low blood lipids, regular physical exercise and smoking cessation can improve health after a stroke. The use of these treatments in routine care has not been successful. Our aim is to study if long-term follow-ups after stroke by specially trained nurses improve the use of the effective treatments mentioned above.

Who can participate?

The participants will be patients diagnosed with a stroke, regardless of age and gender. All patients diagnosed with a stroke in the county of Jämtland during the study period will be assessed for inclusion. The included patients must be able to participate in telephone interviews.

What does the study involve?

The participants will be randomly divided into two groups. One group will be followed up by specially trained nurses. The other group will receive the standard follow-ups in primary healthcare. We will compare the two groups to find out whether the nurse-led follow-ups improve blood pressure, lipid values, exercise habits and smoking cessation.

What are the possible benefits and risks of participating?

There will be no immediate direct benefit to the participants, neither will there be any specific risks. The treatment they will receive is the recommended standard treatment after stroke.

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 2012

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

Who is the main contact?
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 stroke or transient ischemic attack: a randomised, controlled, population-based study

Acronym
NAILED Stroke

Study objectives
The NAILED Stroke risk factor trial (Nurse-based, Age-independent Intervention to Limit Evolution of Disease after Stroke). 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)

Home

Study type(s)

Treatment

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

Stroke

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. 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 patient's 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, 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, low density lipoprotein (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. 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 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

31/12/2016

Eligibility

Key inclusion criteria

1. All patients living in the county of Jämtland, Sweden, and hospitalised with a diagnosis of 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 a suspected stroke or TIA are referred for diagnostic evaluation. A routine for identification of all patients in the hospital with a possible stroke 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

1000

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

31/12/2013

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

+46 (0)63 153000

jamtlands.lans.landsting@jll.se

Sponsor type

Government

Funder(s)

Funder type

Government

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	05/01/2013		Yes	No
Results article	results	14/10/2015		Yes	No
Results article	results	30/04/2016		Yes	No
Results article	results	21/09/2018		Yes	No
Results article	results	15/01/2019		Yes	No
Other publications	Substudy results	11/11/2024	20/11/2024	Yes	No