ISRCTN23868518 https://doi.org/10.1186/ISRCTN23868518

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

Submission date	Recruitment status	[_] Prospectively registered
13/05/2012	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/06/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/11/2024	Circulatory System	

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 Jamtland 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?
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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 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
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Sponsor information

Organisation
Jamtland County Council (Sweden)

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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