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Ambulance transport direct to the stroke unit instead of transport to an emergency department

Submission date
08/04/2022

Recruitment status
No longer recruiting

Registration date
19/04/2022

Overall study status
Completed

Last Edited
18/08/2022

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
A stroke is a serious life-threatening medical condition that happens when the blood supply to part of the brain is cut off. It is a time-sensitive condition and one of the major causes of death and illness worldwide. In Sweden, the yearly incidence of stroke is about 30,000, with a mean age of 75 years, and most patients with stroke need ambulance care. Research and guidelines recommend that care and rehabilitation at a stroke unit should take place immediately in the event of a stroke to improve the recovery of patients. However, for patients with low priority (i.e., not eligible for thrombolysis or thrombectomy), there are delays in the emergency department for CT examination and physical/occupational therapist assessment at a stroke unit. Time to treatment is important and has resulted in more effective prehospital care among these patients. Thus, fast tracks have been developed with the aim of performing a CT scan of the brain as rapidly as possible and transporting the patients directly from the ambulance to the stroke unit, bypassing the emergency department (ED). Although it seems reasonable to assume that transporting the patients from the ambulance directly to a stroke unit is beneficial, there is a lack of evidence of the impact of such a fast track on the early chain of care and on the outcomes. Furthermore, both are considered legitimate standards of care. The aim of this study is to compare direct admission to the stroke unit by ambulance and transport to the ED in terms of time to clinical examination, length of hospital stay and activities of daily living at 3 months.

Who can participate?
Patients aged over 18 years with suspected stroke and cared for by ambulance services in the Region of Halland

What does the study involve?
Participants are randomly allocated by the ambulance nurse before arrival at the hospital to either be directly admitted to the stroke unit by ambulance (DASA) or to be transported to the emergency department (ED). The DASA group are transported directly to the stroke unit and a stroke nurse performs blood tests and sends a referral to the radiology department for CT examination. The neurologist, occupational therapist and physical therapist perform an examination and acute care/rehabilitation. The ED group are transported to the ED. The patient

is prioritized according to the guidelines. An ED nurse carries out blood tests and an ECG. The patient is placed in an examination room or a corridor along with other patients to wait for an examination by a physician. Following examination by the physician, the patient is transported to the radiology department for CT examination and then back to the ED. In the ED, the patient waits for the decision about treatment. Thereafter, the ED nurse reports the patient to the stroke unit, and the patient is moved to the stroke unit.

To investigate if direct admission to the stroke unit by ambulance instead of transport to the emergency department have impact on time to clinical examination, length of hospital stay and ADL at 3 months.

What are the possible benefits and risks of participating?
A possible disadvantage of participation may be that patients do not take part in the emergency department's broad competence if they are randomized to direct admission. At the same time, it can be an advantage to see a doctor directly with a focus on stroke if the patients are subject to direct admission. In both cases, accepted assessment tools are used to support the doctor's initial treatment. Patients who are admitted directly avoid any waiting time at the emergency department.

Where is the study run from?
Halland Hospital and the ambulance services in Region Halland (Sweden)

When is the study starting and how long is it expected to run for?
January 2016 to August 2018

Who is funding the study?
Halland Hospital and the Department of Prehospital Care in Region of Halland (Sweden)

Who is the main contact?
Markus Lingman
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2014/8

Study information

Scientific Title
Direct admission to the stroke unit by ambulance services: a randomized controlled trial comparing two prehospital emergency care pathways and time to clinical examinations, lengths of stay and activities of daily living

Acronym
DASA

Study objectives
Direct admission to a stroke ward by ambulance compared with a standard pathway via the emergency department decreases activities of daily living (ADL) dependence.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/09/2014, Regional Ethical Review Board in Lund, Sweden Dnr 2014/534. Sandgatan. 1, 223 50 Lund, Sweden; +46 (0)46 222 00 00; no email provided), 2014/8

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Stroke

Interventions
Patients assessed with a suspicion of stroke and triaged to level yellow or green (low acuity) according to the Rapid Emergency Triage and Treatment System are randomized using a closed, opaque envelope by the ambulance nurse before arrival to the hospital to either direct admission to the stroke unit by ambulance (DASA) or transport to the emergency department (ED). The patients who are randomized to the DASA group are transported directly to the stroke unit and a stroke nurse performs blood tests and sends a referral to the radiology department for CT examination. Thereafter, the neurologist, occupational therapist and physical therapist perform an examination and acute care/rehabilitation. Patients randomized to the ED are transported to the ED. The patient is prioritized according to the RETTS and ED guidelines. An ED nurse carries out blood tests and an ECG. The patient is placed in an examination room or a corridor along with other patients to wait for examination by a physician. Following examination by the physician, the patient is transported to the radiology department for CT examination and then back to the ED. In the ED, the patient waits for the decision about treatment. Thereafter, the ED nurse reports the patient to the stroke unit, and the patient is moved to the stroke unit.

Intervention Type
Other

Primary outcome measure
Independent in activities of daily living (ADL), mobility, going to the toilet and dressing was measured using patient reported outcome measurements before and three months after the stroke and collected from the Swedish Stroke Registry.

Secondary outcome measures
1. Time in minutes was measured from arrival to admission to stroke unit
2. Time in minutes was measured from arrival to neurologist assessment at stroke unit
3. Time in minutes was measured from arrival to start of computed tomography
4. The number of patients assessed by physical/occupational therapist within 24 h of admission
5. Length of hospital stay was measured in days from arrival to discharge from hospital

Overall study start date
12/01/2016

Completion date
31/08/2018

Eligibility

Key inclusion criteria
1. Patients with a suspected stroke >18 years old and acute onset of a neurological deficit, such as a sudden problem speaking or sudden weakness in the face, arm, or leg
2. Low priority (yellow or green) according to the Rapid Emergency Triage and Treatment System (RETTS)
3. Monday through Friday between 08.00 h and 16.00 h

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
210 patients, with 105 patients in each group

Total final enrolment
2112

Key exclusion criteria
1. Patients who met the criteria for stroke alerts and candidates for i.v. thrombolysis, symptoms for <4 h
2. Plasma glucose of >25 mmol/l
3. Wound damage that needs to be saturated
4. Seizures associated with the disease
5. Diarrhoea or vomiting in the last 48 h

Date of first enrolment
15/01/2016

Date of final enrolment
24/08/2018

Locations

Countries of recruitment
Sweden

Study participating centre
Halland Hospital
Lasarettsvägen
Halmstad
Sweden
30185

Sponsor information

Organisation
Hallands sjukhus Halmstad

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Sponsor type
Hospital/treatment centre

Website
http://www.regionhalland.se/hallandssjukhushalmstad

ROR
https://ror.org/04faw9m73

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Halland Hospital and Department of Prehospital Care, Region of Halland, Sweden

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
15/12/2022

Individual participant data (IPD) sharing plan
The data can be provided after contact with Glenn Larsson, Glenn.larsson@hb.se. Participant-level data is only available if the request is compliant with the related regulatory framework of the European Union and Sweden. Therefore all requests will be treated individually regarding the type of data and availability.

IPD sharing plan summary
Available on request