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Paramedic acute stroke treatment assessment (PASTA)

Submission date
05/11/2015

Recruitment status
No longer recruiting

Registration date
05/11/2015

Overall study status
Completed

Last Edited
30/11/2022

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
A stroke is a serious condition where the blood supply to a part of the brain is cut off, usually by a blood clot blocking an artery or a bleed (haemorrhage). The majority of strokes are ischemic strokes. Ischemic strokes happen when the arteries that supply the brain with oxygen (carotid arteries) become narrowed or blocked, causing severely reduced blood flow (ischemia). As we age, a gradual build-up of a sticky substance called plaque can build-up in one or both of the carotid arteries. When there is a lot of plaque, particularly with a rough or irregular surface, blood clots can develop, depriving the brain of oxygen and leading to an acute ischemic stroke (AIS). This can lead to irreversible damage to the brain and long-term disability if not treated quickly. Thrombolysis, also known as “clot busting”, is a drug treatment that breaks down clots, helping to restore the blood supply to the brain. The quicker this treatment is given, the better the patient’s chance of recovery. Unfortunately, many patients do not receive thrombolysis quickly enough, as the decision to give it relies on specialist assessments, which take place after they have been admitted to hospital. Quicker access to important stroke treatments such as thrombolysis is needed, and paramedics may be able to play a more important role. Paramedic acute stroke treatment assessment (PASTA) is a new care pathway in which paramedics perform an enhanced role in stroke assessment. This involves taking down more information about the patient, providing a structured handover of stroke information to medical professionals and assistance with urgent tasks when they arrive at the hospital with the patient. The aim of this study is to find out whether implementing PASTA could have a beneficial effect on patients’ long-term recovery from an acute stroke.

Who can participate?
Adults who have suffered an acute stroke, and have been assessed by a study paramedic within 4 hours.

What does the study involve?
Study participants receive either the PASTA pathway or usual emergency stroke care, according to the paramedic who attends their emergency call. Before the start of the study, paramedics are randomly allocated to provide the PASTA pathway or to continue with usual emergency stroke care. Participants are also asked to undergo a telephone interview or to complete a postal questionnaire at 90 days after stroke. This records details about recovery after stroke,

including any help required with day to day activities, and rehabilitation received since discharge from hospital.

What are the possible benefits and risks of participating?
The PASTA pathway may improve recovery, but this is not yet proven. There may be no benefits to individuals who take part in the study, however, it is hoped that care for future stroke patients will be improved as a result of this research. There are no notable risks of participating.

Where is the study run from?
North East England, North West England and Wales (UK)

When is the study starting and how long is it expected to run for?
November 2015 to April 2018

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Rachel Lakey

Contact information

Type(s)
Scientific

Contact name
Dr Rachel Lakey

Contact details
Newcastle Clinical Trials Unit, 1-4 , Claremont Terrace
Newcastle upon Tyne
United Kingdom
NE2 4AE

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
20052

Study information

Scientific Title
Paramedic Acute Stroke Treatment Assessment (PASTA)

Acronym
PASTA

Study objectives
The aim of this study is to determine the clinical-and cost-effectiveness of an enhanced Paramedic Acute Stroke Treatment Assessment (PASTA) pathway.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service Committee North East - Newcastle & North Tyneside 1, 09/11/2015, ref: 15/NE/0309

Study design
Cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Topic: Stroke; Subtopic: Acute Care; Disease: In hospital study, Community study

Interventions
Participants will randomly receive either the Paramedic Acute Stroke Treatment Assessment (PASTA) pathway or usual emergency stroke care, according to the paramedic that attends their emergency call. The PASTA pathway is a care pathway where paramedics perform an enhanced role in stroke assessment including additional pre-hospital information collection, structured handover of stroke information at hospital and assistance with urgent tasks on hospital arrival.

Intervention Type
Other

Primary outcome measure
Current primary outcome measure as of 18/12/2019:
Treatment with intravenous thrombolysis on the day of hospital admission assessed by examining medical records

Previous primary outcome measure:
Dependency measured using the modified Rankin Scale (mRS) at 90 days after stroke.

Secondary outcome measures
Current secondary outcome measures as of 18/12/2019:
1. Stroke severity measured by the National Institute of Health Stroke Scale in the medical records at 24 h after thrombolysis
2. Medical complications at 24 h after thrombolysis by examining medical records
3. Dependency assessed using the modified Rankin Scale at discharge from hospital and 90 days after stroke
4. Discharge destination at discharge from hospital assessed by examining medical records
5. Assistance with activities of daily living required at discharge from hospital assessed by examining medical records and at 90 days after stroke by participant interview
6. Residence at 90 days after stroke assessed by examining medical records and participant interview

Previous secondary outcome measures:
1. Stroke severity measured by the National Institute of Health Stroke Scale at 24 hours after thrombolysis
2. Medical complications at 24 hours after thrombolysis
3. Dependency (mRS), discharge destination and assistance with activities of daily living required, at discharge from hospital
4. Residence and assistance with activities of daily living required at 90 days after stroke

Overall study start date
01/01/2015

Completion date
30/04/2019

Eligibility

Key inclusion criteria
Paramedics allocated to delivering the PASTA pathway will be asked to deliver this to the following patients:
1. Aged 18 years and over.
2. Face Arm Speech Test (FAST) positive or any presentation of new focal neurological symptoms which indicate acute stroke in the paramedic's clinical judgement.
3. Within 4 hours of last known to be without new stroke symptoms in the paramedic’s judgement.
4. Admission to a study hospital

Patients will be identified and approached about enrolment in the study after arrival at hospital. Patients approached about enrolment will meet the following criteria:
1. Travelled to hospital with a study paramedic
2. Aged 18 years and over
3. Hospital specialist diagnosis of stroke
4. Within 4 hours of stroke onset (onset time determined by the hospital stroke team) when assessed by the study paramedic

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 3640; UK Sample Size: 3640; Description: The sample sixe is 3640 patients (1820 participants per group)

Total final enrolment
1214

Key exclusion criteria
Not meeting the inclusion criteria

Date of first enrolment
01/12/2015

Date of final enrolment
30/04/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE1 4LP

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

Sponsor details
1st floor
Regent's Point
Regent Farm Road
Newcastle Upon Tyne
England
United Kingdom
NE3 3HD

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The study will be presented at national and international conferences and submitted for publication in peer reviewed journals.

2019 results presented at the European Stroke Organisation Conference in https://eso-wso-conference.org/wp-content/uploads/sites/42/2019/05/PASTA.pdf

Intention to publish date
01/07/2020

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	12/02/2019		Yes	No
Results article	results	01/07/2020	15/04/2020	Yes	No
Results article	economic results	16/03/2021	17/03/2021	Yes	No
Abstract results	V2	22/05/2019	30/11/2022	No	No
Protocol (other)		31/10/2017	30/11/2022	No	No
Results article		01/05/2022	30/11/2022	Yes	No
HRA research summary			28/06/2023	No	No