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Transient ischaemic attack 999 emergency referral

Submission date
23/11/2015

Recruitment status
No longer recruiting

Registration date
01/12/2015

Overall study status
Completed

Last Edited
14/10/2024

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
This is a study of an alternative care pathway (that is, care plan to help patients with a specific condition or symptoms) for patients with low-risk suspected transient ischaemic attack (TIA). TIAs, sometimes referred to as a 'mini stroke', occur when there is a temporary interruption in the flow of blood to the brain. Symptoms may be similar to that of a stroke, for example, difficulty with talking, raising their arms or controlling facial muscles (causing, for example, the face to drop on one side or the patient not being able to smile). To be classed as a TIA, the symptoms must last less than 24 hours. Patients who have a TIA are at risk of having a stroke. How high this risk is depends on the 'severity' of the TIA, which can be assessed with a clinical scoring tool. Those at high-risk should be assessed by a specialist within 24 hours. Guidelines state, however, that patients with low-risk TIA do not require immediate assessment, and can be assessed by a specialist within one week of the TIA. Currently, if a patient calls 999 because they have symptoms of a TIA, paramedics are likely to take them to the emergency department (ED) to be assessed by a doctor. The patient may have to wait several hours to be seen. When the patient is seen by a doctor in the ED, that doctor may refer the patient to TIA clinic, or to the on-call medical doctor. This medical doctor will probably not be a TIA specialist. The outcome of the hospital assessment is, therefore, likely to be a referral to TIA clinic. The patient will have to attend this TIA clinic where a specialist doctor or nurse can assess them again. This duplication of assessment is inconvenient to the patient, and it also wastes NHS resources. This is particularly a problem now, when ED waiting times often exceed the government target of four hours. The aim of this study is to develop and assess the feasibility of paramedic referral pathway of patients with low-risk suspected TIA directly to a TIA clinic for early specialist review, without going to the ED. For those patients who do not require immediate hospital care, this will provide timely specialist review without: adverse consequences; the inconvenience of ED attendance; and cost to the NHS. Patients with high-risk TIA will still be taken to ED.

Who can participate?
All paramedics working in the area where the study is taking place can take part. Patients to be included are those considered to be suffering from a low-risk TIA.

What does the study involve?
Some areas of the UK already have pathways to allow paramedics to directly refer patients to

TIA clinics. Interviews take place with some of the people involved in these pathways to discover how often they are used and if they seem to work well or are problematic. Service user (i.e. involving members of the public) workshops are run to discuss and develop the study with patients providing their perspectives on the problems of existing practice. A review of the literature concerning the prehospital care of patients with suspected TIA is also done. Paramedics are recruited to the study and attend focus groups. The results of the interviews and focus groups are used to help researchers to decide how the pathway tested in this study should work. Paramedics are then randomly allocated to either the intervention group (using the new pathway) or control group (continuing to provide current care). Training is given to the paramedics in the intervention group so that they can safely and appropriately assess and refer patients with suspected TIA. Patients are recruited to the study over the period of one year. An NHS researcher takes the patient's consent to take part in research seven to ten days after their initial 999 call. During the period of patient recruitment, some of the clinicians and managers in the study area are interviewed to get their opinions and ensure there are no concerns with safety. Using the secure anonymised information linkage databank (SAIL), what happens to the participating patients (in either group) are tracked. Patients are contacted after 30 days and also at three months after their initial 999 calls to collect data about their state of health. At the end of the study, patients are interviewed about their experiences and further paramedic focus groups are run to see how their opinions have changed.

What are the possible benefits and risks of participating?
The main benefit for patients with low-risk TIA, is a direct referral to a TIA clinic thus avoiding a lengthy wait in ED to see a doctor unlikely to be a TIA specialist. There may be a risk found in leaving patients at home after they have called 999 without transferring them to ED. However, the National Institute for Health and Care Excellence (NICE) guidance states that patients with low-risk TIA do not require immediate assessment. Any low-risk patients with suspected TIA, assessed as suitable for direct referral to a TIA clinic and therefore left at home, will be appropriately informed of their health condition and the rationale for this clinical decision. They will be provided with a Patient Information Leaflet, including instructions that, should they experience another TIA, especially if it is within one week of the initial episode, that they should call 999 again. Any low-risk patient who wishes to attend hospital in preference to being referred directly to TIA clinic, will be taken to the ED. All high-risk patients will still be transferred to ED.

Where is the study run from?
Welsh Ambulance Services NHS Trust (UK)

When is the study starting and how long is it expected to run for?
October 2015 to September 2017

Who is funding the study?
Health and Care Research Wales.

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1053

Study information

Scientific Title
Transient ischaemic attack 999 emergency referral: a pragmatic cluster randomised feasibility trial

Acronym
TIER

Study objectives
This feasibility trial aims to develop and assess the feasibility of a paramedic referral pathway of patients with low-risk suspected transient ischaemic attack (TIA) directly to TIA clinic for early specialist review, without going to the Emergency Department.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wales REC 3, 12/05/2016, ref: 16/WA/0116

Study design
This feasibility trial is a pragmatic cluster randomised trial with random allocation by paramedic.

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Home

Study type(s)
Other

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
Transient ischaemic attack (TIA)

Interventions
The intervention is a complex package including paramedic training; a risk stratification checklist for assessing patients with suspected TIA; and a referral protocol and process. At the core of the intervention is the protocol to support assessment and decision-making.

In accordance with Medical Research Council (MRC) guidance, paramedics will be randomised rather than patients, since the intervention targets health professionals with the aim of studying effects on patient outcomes.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Time to subsequent emergency contact (999 call or ED attendance) or death
2. Time to specialist assessment by a stroke consultant or TIA specialist nurse

Secondary outcome measures
1. Outcome of contact: whether patient is taken to hospital or left at home and referred or left at home but not referred, together with time from onset to additional therapy; and attendance at TIA clinic (who and when)
2. Health care utilisation in one month and three months following contact
3. Patient-reported outcomes: satisfaction with care received (Quality of Care Monitor); health status (SF-12) at one month and three months
4. Costs of implementation, and costs of care and consequences per patient
5. Appropriateness of clinical management

Overall study start date
01/10/2015

Completion date
30/09/2017

Eligibility

Key inclusion criteria
Patients will be eligible for the study if they are:
1. Attended by a trial paramedic during the recruitment period
2. Coded as low-risk suspected TIA by the attending paramedic using the standard tool
3. Attended in the catchment area of the two hospitals taking part in the trial

All paramedics working in within the study area are eligible

Participant type(s)
Mixed

Age group
All

Sex
Both

Target number of participants
The target recruitment of paramedic participants is 60 - 70. The target number of patients is 86, 43 intervention/43 control.

Key exclusion criteria
There are no exclusion criteria for paramedics.

Patient exclusion criteria:
1. Unable to give informed consent (lacks capacity)
2. Apparent or known cognitive impairment (such as a diagnosis of dementia), due to the potential for inaccuracies in the reporting of symptoms
3. Patients with crescendo TIAs (i.e. patient has had similar symptoms within the last week)
4. Patients with ongoing symptoms (i.e. cannot definitely be classified as a TIA)

Date of first enrolment
01/02/2016

Date of final enrolment
31/03/2017

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre

Welsh Ambulance Services NHS Trust
Pre-hospital Emergency Research Unit
Lansdowne Hospital
Sanatorium Road
Cardiff
United Kingdom
CF11 8UL

Sponsor information

Organisation
Welsh Ambulance Services NHS Trust

Sponsor details
Pre-hospital Emergency Research Unit
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United Kingdom
CF11 8UL

Sponsor type
Not defined

ROR
https://ror.org/017qpw206

Funder(s)

Funder type
Government

Funder Name
Health and Care Research Wales

Results and Publications

Publication and dissemination plan
We will share the findings from this study widely. This will be to patient, policy, academic and clinical audiences. We will publish in an open access journal, on a website, and present at conferences. The service users involved in this research will be encouraged to help share findings from this trial, particularly via patient forums, and also present their involvement

experiences at the Involving People Annual Meeting and the bi-annual INVOLVE Conference. We plan to publish the protocol in early 2016. The final report will be published the year after the feasibility trial ends and the results will be published in a scientific journal as soon as possible after the end of the feasibility trial in October 2017.

2018 results in a poster: http://www.primecentre.wales/resources/TIER%20Int%20Dev%20and%20Usage%20Poster_2018.pdf

Intention to publish date
31/03/2016

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	scoping review	14/02/2017	10/12/2020	Yes	No
Abstract results			14/11/2022	No	No
HRA research summary			28/06/2023	No	No
Results article		10/10/2024	14/10/2024	Yes	No