

Improving the prevention of vascular events after stroke or transient ischemic attack

Submission date 17/05/2012	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 17/05/2012	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 12/02/2018	Condition category Circulatory System	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
9026

Study information

Scientific Title
IMproving the PRevention Of Vascular Events after stroke or transient ischemic attack: a randomised controlled pilot trial of nurse independent prescriber-led care pathway-based risk factor management

Acronym
IMPROVE

Study objectives

Our pilot trial will be trying to improve the treatment of risk factors like blood pressure after a mini-stroke. The trial will compare usual care (having your risk factors treated the way they are at the moment, usually by visits to the GP with an approach that puts treatment in the hands of a new type of nurse, who will prescribe treatment according to a specially-designed plan called a care pathway. We are hoping this will mean that the persons risk factors will be better controlled, and their risk of another stroke is reduced. We will check on peoples blood pressure using an automatic arm cuff during normal activities an ambulatory monitor, which gives a more reliable result than measurements taken in the clinic. After six months and again after a year we will compare the effects of treatment between usual care and the new approach, to see if one is better than the other.

Any treatment is only effective if people can stick with it, and we know that a lot of people on prescribed drugs give up taking them for various reasons. In this trial people will get the chance to tell the researchers the good and bad things about taking part, and whether the new type of nurse-led care pathway worked for them. This is important so that we can understand the things that would help people to stay on treatment. If our pilot is successful, we will go ahead with a larger study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
ref: 10/H0106/46

Study design
Randomised interventional prevention process of care trial

Primary study design
Interventional

Study type(s)
Prevention

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

Interventions
Secondary Prevention algorithm, Nurse Independent Prescriber-led, care pathway-based secondary vascular risk factor management.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)

Ambulatory 12-hour daytime systolic blood pressure measured at 6 months

Key secondary outcome(s)

No secondary outcome measures

Completion date

09/09/2011

Eligibility

Key inclusion criteria

1. Clinical diagnosis of transient ischemic attack (TIA) or stroke within one month
2. Patient is living at home at time of recruitment
3. Age $\geq$ 18 years
4. Systolic blood pressure (SBP) $>$ 140 mmHg measured at time of diagnosis of stroke or TIA
5. Registered with a general practitioner (GP) in one of the two pilot clusters (Exeter and East Devon)
6. Ability to attend for follow-up visits
7. Given informed consent
8. Male or female participants

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Severe dementia or aphasia
2. Significant co-morbidity likely to jeopardise ability to complete the trial e.g. malignancy, severe heart failure
3. Current participation in other trials

Date of first enrolment

04/01/2011

Date of final enrolment

09/09/2011

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Royal Devon & Exeter Hospital

Exeter

United Kingdom

EX2 5DW

Sponsor information

Organisation

Royal Devon and Exeter Foundation Trust (UK)

ROR

<https://ror.org/03085z545>

Funder(s)

Funder type

Government

Funder Name

NIHR Research for Patient Benefit Programme (UK)

Results and Publications

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?
HRA research summary			28/06/2023	No	No