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

Submission date	Recruitment status	[ ] Prospectively registered
17/05/2012	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
17/05/2012	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
12/02/2018	Circulatory System	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

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

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

Secondary outcome measures
No secondary outcome measures

Overall study start date
04/01/2011

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. Ag e> 18 years
4. Systolic blood pressure (SBP) > 140 mmHg measured at time of diagnosis of stroke or TIA
5. Registered with ageneral practitioner (GP) in one of the two pilot clusters (Exete and East Devon)
6. Ability to attend for follow-up visits
7. Given iInformed consent
8. Male or female participants

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 30

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
England

United Kingdom

Study participating centre
Royal Devon & Exeter Hospital
Exeter
United Kingdom
EX2 5DW

Sponsor information

Organisation
Royal Devon and Exeter Foundation Trust (UK)

Sponsor details
Royal Devon & Exeter Hospital
Barrack Road
Exeter
England
United Kingdom
EX2 5DW
+44 (0)1392 411611
abc@email.com

Sponsor type
Hospital/treatment centre

Website
http://www.rdehospital.nhs.uk/

ROR
https://ror.org/03085z545

Funder(s)

Funder type
Government

Funder Name
NIHR Research for Patient Benefit Programme (UK)

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?
HRA research summary			28/06/2023	No	No