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Effectiveness and cost effectiveness of self-monitoring and treatment of blood pressure in secondary prevention following stroke or transient ischaemic attack

Submission date
10/06/2015

Recruitment status
No longer recruiting

Registration date
10/06/2015

Overall study status
Completed

Last Edited
17/02/2020

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
This study aims to compare different ways of measuring and managing high blood pressure after a stroke or ministroke (TIA). At present, decisions about whether blood pressure levels need to be treated and therefore how much and what blood pressure lowering treatment to take are usually based on blood pressure levels taken at the hospital clinics or GP surgeries. It is not known whether self-monitoring of blood pressure with some guidance and adjustment of medication would improve the blood pressure control and hence reduce the risk of stroke in people who have had a TIA and milder stroke. The aim of this study is to test whether self-monitoring of blood pressure and supervised self-management of treatment results in better blood pressure control and greater patient satisfaction.

Who can participate?
Patients aged 55 and over with TIA or stroke who require blood pressure management

What does the study involve?
Participants are randomly allocated to one of three groups. The first group monitor their blood pressure and manage their own treatment changes with the study team’s support. The second group monitor their blood pressure but the results are relayed to a participant's GP, with GP-led treatment changes. The third group undergoes standard GP clinic blood pressure measurements. All the participants’ blood pressure levels are assessed after 6 months and they are asked how they feel about home monitoring of blood pressure in terms of how easy and practical it is, what concerns they may have and how they feel about altering their treatment under supervision. This study also assesses whether blood pressure self-monitoring represents good value for money for the NHS and taxpayers.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Norfolk and Norwich University Hospital NHS Trust (UK)

When is the study starting and how long is it expected to run for?
November 2012 to September 2016

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

Who is the main contact?
John Potter

Contact information

Type(s)
Scientific

Contact name
Dr John Potter

Contact details
Norfolk and Norwich University Hospital NHS Trust
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Additional identifiers

ClinicalTrials.gov (NCT)
NCT02947490

Protocol serial number
11032

Study information

Scientific Title
Trial of the effectiveness and cost effectiveness of selfmonitoring and treatment of blood pressure in secondary prevention following stroke or transient ischaemic attack

Acronym
TEST BP

Study objectives
This study aims to compare different ways of measuring and managing high blood pressure after a stroke or ministroke (TIA).

Ethics approval required

Old ethics approval format

Ethics approval(s)
11/EE/0147

Study design
Randomised; Interventional; Design type: Not specified

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Stroke; Subtopic: Primary Care, Rehabilitation; Disease: Therapy type

Interventions
1. Self monitoring of Blood Pressure (SBPM) with supervised patient lead treatment changes
2. SBPM only with GP lead treatment changes
3. Standard GP lead control and no SBPM

Follow Up Length: 6 month(s); Study Entry : Single Randomisation only

Intervention Type
Other

Phase
Phase III

Primary outcome(s)
Ambulatory BP levels and control at 6 months; Timepoint(s): ABPM at 6 months after randomisation

Key secondary outcome(s))
N/A

Completion date
30/09/2016

Eligibility

Key inclusion criteria
1. Age >= 55 years
2. Patients with TIA or stroke of mild/moderate severity (NIHSS =<15)
3. Patients that require BP management
4. Patients able and willing to undertake self BP measurement and guided alterations in therapy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients with terminal illness with life expectancy less than six months including end staged condition e.g. end stage COPD Dementia
2. Patients with moderate to severe cognitive impairment
3. Patients not receiving or expected to start antihypertensive therapy

Date of first enrolment
01/11/2012

Date of final enrolment
30/09/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Norfolk and Norwich University Hospital NHS Trust
Colney Lane
Colney
Norwich, Norfolk
United Kingdom
NR4 7UY

Sponsor information

Organisation
Norfolk and Norwich University Hospital NHS Trust

ROR
https://ror.org/01wspv808

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

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?
Results article	results	01/09/2018	23/01/2019	Yes	No
Results article	results	01/01/2019	23/01/2019	Yes	No
Other publications	economic evaluation	01/09/2020	17/02/2020	Yes	No