ISRCTN35701810 https://doi.org/10.1186/ISRCTN35701810

# Secondary prevention after first stroke

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|---|---|---|
| **Submission date**<br>16/03/2010 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[X] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>17/03/2010 | **Overall study status**<br>Completed | |
| **Last Edited**<br>09/06/2014 | **Condition category**<br>Circulatory System | |

**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**
086921

## Study information

## Scientific Title
Cluster randomised trial in a Primary Care database: utilising electronic patient records for intervention research into secondary prevention after first stroke

## Study objectives
We aim to provide proof of concept of the feasibility and utility of implementing cluster randomised trials utilising electronic patient records in a large national primary care database.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
London - Surrey Borders Research Ethics Committee approved on the 13th January 2010 (ref: 10 /H0806/1)

## Study design
Interventional multicentre clustered randomised 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 below to request a patient information sheet

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

## Interventions
A series of electronic prompts will be activated at each consultation by patients with previous stroke, to promote adherence with evidence-based recommendations for secondary prevention of stroke and vascular disease following the National Guidelines (Intercollegiate Stroke Working Party [ICSWP], 2008). The prompts encourage primary care professional adherence with recommended processes of care. The prompts will also provide them with supporting information and links to evidence that supports the recommendations. The decision on whether to follow the treatment suggestions included in the prompt will be at the discretion of the GP. The GP will also be able to terminate display of the prompt at any time. Control practices will continue with usual care. The intervention will be implemented for 12 months at each practice.

## Intervention Type
Other

### Phase
Not Applicable

### Primary outcome measure
Difference in mean systolic blood pressure (BP) between intervention and control groups at 12 months adjusted for pre-intervention mean systolic BP

### Secondary outcome measures
Measured at 12 months follow-up:
1. Mean diastolic blood pressure
2. Mean cholesterol concentration
3. Proportion of patients whose eligibility for anticoagulants/antiplatelet drugs is defined
4. Proportion of eligible patients that receive anticoagulant/antiplatelet drugs
5. Prescription adherence with prescribed medicines
6. Occurrence and hospitalisation with vascular events including transient ischaemic attack (TIA) /stroke, myocardial infarction, new-onset angina and mortality

### Overall study start date
01/04/2010

### Completion date
31/10/2011

## Eligibility

### Key inclusion criteria
1. All stroke patients (no age limit, either sex)
2. Registered at the practice for at least three years at the trial start date
3. First diagnosis of stroke recorded in the 24 month period before the trial start date
4. Medical code for stroke is entered during the consultation
5. Patient's electronic medical record includes previous stroke medical codes

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
50 GP practices per group (100 practices in total)

### Key exclusion criteria
No eligible patients will be excluded from the analysis, to avoid bias.

### Date of first enrolment
01/04/2010

**Date of final enrolment**
31/10/2011

# Locations

**Countries of recruitment**
England

United Kingdom

**Study participating centre**
**Division of Primary Care and Public Health**
London
United Kingdom
SE1 3QD

# Sponsor information

**Organisation**
The Wellcome Trust (UK)

**Sponsor details**
Gibbs Building
215 Euston Road
London
United Kingdom
NW1 2BE
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**Sponsor type**
Charity

**Website**
http://www.wellcome.ac.uk/

**ROR**
https://ror.org/029chgv08

# Funder(s)

**Funder type**
Charity

**Funder Name**
The Wellcome Trust (UK) (grant ref: 086921)

# 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? |
|---|---|---|---|---|---|
| Protocol article | protocol | 03/10/2012 | | Yes | No |
| Results article | results | 01/07/2014 | | Yes | No |