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Secondary prevention after first stroke

Submission date 16/03/2010	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 17/03/2010	**Overall study status** Completed	
Last Edited 09/06/2014	**Condition category** 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
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215 Euston Road
London
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NW1 2BE
contact@wellcome.ac.uk

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