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

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

Protocol serial number
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)

Primary study design
Interventional

Study design
Interventional multicentre clustered randomised trial

Study type(s)
Prevention

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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Study participating centre

Division of Primary Care and Public Health
London
United Kingdom
SE1 3QD

Sponsor information

Organisation
The Wellcome Trust (UK)

ROR
https://ror.org/029chgv08

Funder(s)

Funder type
Charity

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

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	01/07/2014		Yes	No
Protocol article	protocol	03/10/2012		Yes	No