ISRCTN97412358 https://doi.org/10.1186/ISRCTN97412358

ECG monitoring to detect atrial fibrillation after stroke

Submission date	Recruitment status	[X] Prospectively registered
18/03/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/04/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/03/2016	Circulatory System	

Plain English summary of protocol

Background and study aims
Atrial fibrillation is a heart condition that causes an irregular heart rate. It can cause blood clots in the heart, which can break up, escape from the heart and become lodged in the blood vessels supplying the brain, causing a stroke. Stroke patients with atrial fibrillation are therefore at a higher risk of having another stroke, but atrial fibrillation is not always identified by the standard investigations performed after a stroke. An electrocardiogram (ECG) is a simple test to check the heart's rhythm and electrical activity. The aim of this study is to find out whether additional ECG monitoring early after stroke speeds up the detection of atrial fibrillation and the start of effective treatment.

Who can participate?
Patients who have had a stroke in the last week

What does the study involve?
Participants are randomly allocated to one of two groups. One group receives standard care, and the other group receives additional ECG monitoring (two additional 12-lead ECGs plus 3 to 7 days' continuous ECG event monitoring). We assess the number of patients with detected atrial fibrillation and starting treatment for atrial fibrillation, the costs of investigation and treatment, patient acceptability, stroke recurrence, quality of life and survival in the two groups.

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

Where is the study run from?
Western Infirmary (UK)

When is the study starting and how long is it expected to run for?
May 2010 to December 2016

Who is funding the study?
Chief Scientist Office of the Scottish Executive Health Department (UK)

Who is the main contact?
Prof. Kennedy Lees
k.r.lees@clinmed.gla.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Kennedy R Lees

Contact details
Acute Stroke Unit & Cerebrovascular Clinic
Western Infirmary
44 Church Street
and
Cardiovascular & Medical Sciences
Faculty of Medicine
University of Glasgow
Glasgow
United Kingdom
G11 6NT
-
k.r.lees@clinmed.gla.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Evaluation of electrocardiographic monitoring strategy to identify atrial fibrillation in patients with recent acute stroke: a randomised controlled trial

Study objectives
Intensive investigation for atrial fibrillation amongst patients with acute stroke or confirmed transient ischaemic attack (TIA) who are admitted or initially assessed in sinus rhythm will detect 5% who have unrecognised episodes of atrial fibrillation/flutter; and 3.5% who will be suitable to commence oral anticoagulation, rendering a policy of more intensive investigation cost-effective in the NHS.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Scotland A Research Ethics Committee, 17/08/2009, ref: 09/MRE00/59

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

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
Ischaemic stroke

Interventions
Control: standard care
Intervention: two additional 12-lead ECGs plus 3 - 7 days' continuous ECG event monitoring

Duration of intervention: 7 days
Duration of follow-up: 1 year direct; 5 years electronic

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Absolute number of patients with AF or atrial flutter detected within two weeks of stroke.

Secondary outcome measures
Secondary outcomes:
1. Absolute number of patients with AF or atrial flutter detected within 90 days and one year of stroke
2. Absolute number of patients commenced on oral anticoagulation within two weeks and one year of stroke

3. Marginal cost of investigation
4. Marginal cost of treatment
5. Patient acceptability
6. Time to recognition of AF/flutter

Tertiary outcomes:
1. Stroke recurrence within one year
2. Distribution of modified Rankin scale at one year (assessed centrally by recorded interview to ensure objectivity)
3. 'Home time' over 90 days - an objective measure of early functional outcome
4. EQ-5D quality of life at one year (in patients who can complete this, or by proxy)
5. Five-year survival (by flagging with ONS)
6. Predictors of AF amongst eligible patients
7. AF duration 'threshold' for use of anticoagulation

Overall study start date
01/05/2010

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. Diagnosis of acute ischaemic stroke or confirmed transient ischaemic attack, within one week of symptom onset (participants are of any age and sex)
2. Brain imaging completed prior to enrolment is consistent with acute ischaemic damage and has excluded an alternative cause for symptoms
3. Sinus rhythm on screening ECG
4. Consent to participate from patient or approved proxy

Participant type(s)
Patient

Age group
All

Sex
Both

Target number of participants
5000

Key exclusion criteria
1. Clinical decision or expressed refusal to consider long term anticoagulation at a future date if cardio-embolism may be diagnosed
2. Pre-morbid condition or concomitant disease that would render subsequent secondary prevention of stroke inappropriate
3. Documented atrial fibrillation in past
4. Known durable cardiac source of embolism (eg mitral stenosis) or left ventricular akinesia,

that would represent an indication for anticoagulation
5. Existing treatment with long term anticoagulation
6. Unlikely to be available for completion of study procedures

Date of first enrolment
01/05/2010

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Western Infirmary
Glasgow
United Kingdom
G11 6NT

Sponsor information

Organisation
NHS Greater Glasgow & Clyde (UK)

Sponsor details
Research and Development Central Office
Western Infirmary
1st Floor, Tennent Institute
38 Church Street
Glasgow
United Kingdom
G11 6NT

Sponsor type
Government

Website
http://www.nhsggc.org.uk/r&d

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

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?
Results article	results	01/09/2013		Yes	No
HRA research summary			28/06/2023	No	No