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# 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
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# Contact information

### Type(s)
Scientific

### Contact name
Prof Kennedy R Lees

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# Additional identifiers

### Protocol serial number
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

## Study type(s)
Diagnostic

## 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(s)
Absolute number of patients with AF or atrial flutter detected within two weeks of stroke.

## Key secondary outcome(s))
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

## 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

### Healthy volunteers allowed
No

### Age group
All

### Sex
All

### 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
United Kingdom

Scotland

### Study participating centre

**Western Infirmary**
Glasgow
United Kingdom
G11 6NT

# Sponsor information

**Organisation**
NHS Greater Glasgow & Clyde (UK)

**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

**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 |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |