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A randomised controlled trial to investigate the clinical and cost effectiveness of adding an ablation device-based maze procedure as a routine adjunct to elective cardiac surgery for patients with pre-existing atrial fibrillation

Submission date 04/04/2008	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 04/04/2008	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 30/03/2022	**Condition category** Circulatory System	[_] Individual participant data

Plain English summary of protocol

Background and study aims

Atrial fibrillation (AF) is a fast irregular heart beat caused by abnormal electrical signalling. It is very common (affecting 1 in 20 middle aged people and 1 in 10 aged over 80) and the high risk of clotting leads to stroke in 1 in 25 AF patients if left untreated. AF patients are therefore given blood thinning drugs. These reduce strokes by about two thirds but can cause bleeding so patients need careful monitoring. In short, the complications and treatment of AF all reduce the patient's quality of life and are very costly for the NHS. The 'maze' procedure is major surgery which involves cutting and stitching the atrial wall to re-direct electrical signals down the correct paths. It can stop AF but is not widely used due to its complexity. However, ablation devices are now available that can be used to make a 'maze' procedure simpler, quicker and safer. The marketing of these devices claims that they can restore normal heart rhythm when incorporated into a routine heart operation. However, this needs evaluation before the technology creeps into practice. The aim of this study is to find out whether adding this costly technology to routine heart surgery is worthwhile for the patients and for the NHS.

Who can participate?

Patients aged over 18 with atrial fibrillation who are undergoing elective heart surgery

What does the study involve?

Participants are randomly allocated to undergo heart surgery either with or without the ablation device-based maze procedure. Survival, quality of life and cost effectiveness are compared between the two groups.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?
Papworth Hospital NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
September 2008 to February 2012

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

Protocol serial number
HTA 07/01/34

Study information

Scientific Title
A randomised controlled trial to investigate the clinical and cost effectiveness of adding an ablation device-based maze procedure as a routine adjunct to elective cardiac surgery for patients with pre-existing atrial fibrillation

Acronym
AMAZE

Study objectives
Treating a patient's atrial fibrillation (AF) by incorporating a modified maze procedure (using an AF ablation device) into their elective cardiac surgery will improve their quality of life as well as being cost effective from an NHS perspective.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/070134
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0020/51716/PRO-07-01-34.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Pending, to be submitted as of 04/04/2008

Study design
Multi-centre prospective randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Patients with pre-existing atrial fibrillation (AF) requiring elective cardiac surgery

Interventions
Elective cardiac surgery with or without addition of ablation device-based maze procedure as adjunct.

Intervention Type
Device

Phase
Not Applicable

Primary outcome(s)
Patient benefit will be assessed by the following:
1. Rate of return to stable sinus rhythm (SR) at 12 months. Seven-day electrocardiogram (ECG)

monitors will be used to assess the predominant rhythm (SR or AF) and the AF load i.e. the percentage of time that the patient is in AF if their predominant rhythm is SR
2. Quality-adjusted survival over 2 years

Key secondary outcome(s))
The following will be assessed at 6, 12 and 24 months and annually thereafter, except where indicated otherwise:
1. Cost-effectiveness for the NHS will be assessed by collecting resource use data and costs incurred by both groups and comparing their costs per quality-adjusted life year (QALY). Further longer term economic modelling will also be undertaken.
2. Other secondary objectives will be to determine whether the adjunct ablation device-based procedure:
2.1. Improves the rate of return to stable SR at 24 months after surgery
2.2. Improves atrial function (i.e. increases atrial transport assessed by echocardiography)
2.3. Decreases thromboembolic neurological complications (e.g. stroke)
2.4. Enables anticoagulant treatment to be withdrawn safely
2.5. Enables safe reduction or withdrawal of antiarrhythmic medication

Completion date
29/02/2012

Eligibility

Key inclusion criteria
1. Age over 18, both males and females
2. Patients will have elective cardiac surgery planned (coronary surgery, valve surgery, combined coronary and valve surgery, any other cardiac surgery requiring cardiopulmonary bypass)
3. Patients will have a history of documented atrial fibrillation (chronic, persistent or paroxysmal) beginning more than 3 months before entry into the study
4. All patients will provide written informed consent to participation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
352

Key exclusion criteria

1. Patients with previous cardiac operations
2. Patients having emergency or salvage cardiac operations
3. Patients whose surgery will not involve cardiopulmonary bypass
4. Patients who are unlikely to be available for follow-up over a two-year period
5. Patients who are deemed not competent to provide consent

Date of first enrolment
01/09/2008

Date of final enrolment
29/02/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Papworth Hospital NHS Foundation Trust
Cambridge
United Kingdom
CB23 3RE

Sponsor information

Organisation
Papworth Hospital NHS Foundation Trust (UK)

ROR
https://ror.org/01qbebb31

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2018		Yes	No
Results article	five-year results	26/03/2022	30/03/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes