

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/04/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 30/03/2022	Condition category Circulatory System	<input type="checkbox"/> 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?
Dr Hester Goddard
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

01/09/2008

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

400

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**

England

United Kingdom

Study participating centre

Papworth Hospital NHS Foundation Trust

Cambridge

United Kingdom

CB23 3RE

Sponsor information

Organisation

Papworth Hospital NHS Foundation Trust (UK)

Sponsor details

c/o Dr Hester Goddard

R&D Unit

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Papworth Hospital NHS Foundation Trust

Papworth Everard

Cambridge

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United Kingdom

CB23 3RE

+44 (0)1480 364181

hester.goddard@papworth.nhs.uk

Sponsor type

Hospital/treatment centre

Website

<http://www.papworthhospital.nhs.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, HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

01/07/2017

Individual participant data (IPD) sharing plan

Not provided at time of registration

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	01/04/2018		Yes	No
Results article	five-year results	26/03/2022	30/03/2022	Yes	No