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Reducing stroke rates using left atrial appendage occlusion

Submission date	Recruitment status	[_] Prospectively registered
09/03/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/03/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/06/2022	Circulatory System	

Plain English summary of protocol

Background and study aims
Atrial fibrillation (AF) is a common heart condition, affecting millions of people worldwide. The heart consists of two upper chambers (atria) and two lower chambers (ventricles). Inside the right atrium, a cluster of cells (sinus node) are responsible for firing electrical signals into the heart muscle causing the heart to beat regularly (sinus rhythm). When a person is suffering from AF, the normal signals from the sinus node do not work properly, causing other parts of the atria to fire chaotically. These uncoordinated signals cause the heart to beat irregularly and often very fast (arrhythmia). People suffering from AF have a much higher risk of developing other problems, such as stroke. Prevention of stroke in people with AF is usually achieved using blood thinning medications such as colchicine however this is not always effective and there is a risk of serious bleeding. The left atrial appendage is a small structure in the muscle wall of the left atrium and is thought to be the most common source of blood clots causing stroke in patients with AF. Left atrial appendage closure (LAAC) is a treatment strategy which has been an area of interest in the field of stroke prevention. Blocking off (occluding) this structure during surgery using a suture (stitch) or surgical stapler, could be an effective method of stroke prevention in these patients, removing the need to take blood thinners. The aim of this study is to find out whether left atrial appendage occlusion can help to lower the occurrence of stroke in AF patients.

Who can participate?
Adults with AF who are having heart surgery involving a cardiopulmonary bypass.

What does the study involve?
Participants are randomly allocated to one of two groups. For those in the first group, during their surgery, the surgeon will block off (occlude) the left atrial appendage using a suture (stitch) and/or surgical stapler. For those in the second group, the left atrial appendage is not closed during surgery. Participants in both groups are followed up in order to find out which group has the higher occurrence of stroke.

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

Where is the study run from?
Hammersmith Hospital (UK)

When is the study starting and how long is it expected to run for?
November 2015 to December 2017

Who is funding the study?
Canadian Institutes for Health Research (UK)

Who is the main contact?
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Public

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT01561651

Protocol serial number
19759

Study information

Scientific Title
Left Atrial Appendage Occlusion Study III (LAAOS III)

Study objectives
The aim of this study is to examine the impact of left atrial appendage occlusion on the incidence of stroke or systemic arterial embolism in patients with atrial fibrillation undergoing cardiac surgery over the duration of follow -up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
15/LO/0769

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Cardiovascular; Subtopic: Cardiovascular (all Subtopics); Disease: Cardiac Surgery

Interventions
Participants are randomly allocated to one of two groups.

Intervention group: Surgeon will occlude the left atrial appendage using a suture and/or a surgical stapler or a regulatory approved atrial appendage closure during the patient's cardiac surgery procedure.

Control group: Surgeon will not close the left atrial appendage during the patient's cardiac surgery procedure.

Intervention Type
Other

Phase
Phase III

Primary outcome(s)
First occurrence of stroke or systemic arterial embolism over the duration of follow-up.

Key secondary outcome(s))
Not provided at time of registration

Completion date
30/04/2021

Eligibility

Key inclusion criteria
1. Aged 18 years or above
2. Undergoing a clinically indicated cardiac surgical procedure with the use of cardiopulmonary bypass
3. A documented history of atrial fibrillation or atrial flutter
4. CHA2DS2--VASc score ≥ 2
5. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
4811

Key exclusion criteria
1. Patients undergoing any of the following procedures:
1.1. Off--pump cardiac surgery
1.2. Heart transplant
1.3. Complex congenital heart surgery
1.4. Sole indication for surgery is ventricular assist device insertion
1.5. Previous cardiac surgery (re-operation)
1.6. Mechanical valve implantation
2. Patients who have had a previous placement of a percutaneous LAA closure device

Date of first enrolment
30/11/2015

Date of final enrolment
04/09/2018

Locations

Countries of recruitment
United Kingdom

England

Argentina

Australia

Austria

Belgium

Brazil

Canada

China

Colombia

Czech Republic

Egypt

Germany

Greece

Hong Kong

India

Iran

Ireland

Italy

Japan

Malaysia

Netherlands

New Zealand

Poland

Portugal

Russian Federation

Spain

Switzerland

United States of America

Study participating centre
Hammersmith Hospital
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Sponsor information

Organisation
Imperial College Healthcare NHS Trust

ROR
https://ror.org/056ffv270

Funder(s)

Funder type
Government

Funder Name
Canadian Institutes of Health Research

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

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		03/06/2021	07/06/2022	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes