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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?
1. Mr Sajiram Sarvananthan (public)
s.sajiram@imperial.ac.uk
2. Mr Prakash Punjabi (scientific)
p.punjabi@imperial.ac.uk

# Contact information

### Type(s)
Public

### Contact name
Mr Sajiram Sarvananthan

### Contact details
Imperial College Healthcare NHS Trust
Hammersmith Hospital
Du Cane Road
London
United Kingdom
W12 0HS
+44 7949 554467
s.sajiram@imperial.ac.uk

### Type(s)
Scientific

### Contact name
Mr Prakash Punjabi

### Contact details
Hammersmith Hospital
Department Of Cardiothoracic Surgery
Du Cane Road
London
United Kingdom
W12 0HS
+44 208 383 2026
p.punjabi@imperial.ac.uk

# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number
NCT01561651

### Secondary identifying numbers
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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Other

### Study type(s)
Treatment

### 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
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 measure
First occurrence of stroke or systemic arterial embolism over the duration of follow-up.

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
30/11/2015

### 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
Planned Sample Size: 4700; UK Sample Size: 200

### 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
Argentina

Australia

Austria

Belgium

Brazil

Canada

China

Colombia

Czech Republic

Egypt

England

Germany

Greece

Hong Kong

India

Iran

Ireland

Italy

Japan

Malaysia

Netherlands

New Zealand

Poland

Portugal

Russian Federation

Spain

Switzerland

United Kingdom

United States of America

### Study participating centre
**Hammersmith Hospital**
Imperial College Healthcare NHS Trust
Du Cane Road
London
United Kingdom
W12 0HS

# Sponsor information

### Organisation
Imperial College Healthcare NHS Trust

### Sponsor details
Hammersmith Hospital
Du Cane Road
London
England

United Kingdom
W12 0HS

**Sponsor type**
Hospital/treatment centre

**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, IRSC

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
Canada

# Results and Publications

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**
15/05/2021

**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 | | 03/06/2021 | 07/06/2022 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |