

Septal closure of patent foramen ovale: does it prevent migraine?

Submission date 11/04/2007	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 11/04/2007	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 01/02/2019	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
<http://www.pfo-lumc.nl>

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00369499

Secondary identifying numbers

N/A

Study information

Scientific Title

Septal closure of patent foramen ovale: does it prevent migraine?

Acronym

STOP PAIN

Study objectives

The primary objective of the study STOP PAIN is to compare the effect on migraine attack frequency of transcatheter device closure of atrial shunting with a non-closure group in migraine patients suffering severe migraine with aura.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval pending from the LUMC ethics committee.

Study design

Randomised, placebo controlled, parallel group, double blind, multicentre trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Migraine, foramen ovale persistens, closure

Interventions

In migraine patients with aura who have a patent foramen ovale, transcatheter device closure PFO after randomisation will be performed, versus a sham procedure.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Number of patients experiencing 50% reduction of migraine in closure group compared with sham group.

Outcomes will be measured monthly from three to nine months after closure.

Secondary outcome measures

1. Mean values of monthly migraine periods
2. Quality of Life (QoL) using headache impact test questionnaire

Outcomes will be measured monthly from three to nine months after closure.

Overall study start date

01/04/2007

Completion date

01/04/2008

Reason abandoned (if study stopped)

Participant recruitment issue

Eligibility

Key inclusion criteria

1. Migraine with aura
2. Migraine history of at least one year:
 - a. at least two migraine attacks/month
 - b. at least one migraine attack with aura
3. Failure or intolerance to two classes prophylactic migraine medication
4. Aged 18 to 50 years
5. Right to left shunt suitable for closure

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

50

Key exclusion criteria

1. History of 15 or more headache days per month
2. Taking preventive medication for other conditions other than migraine
3. Eight or more non-migraine headache days/month
4. Overuse of acute headache medication (use on ten or more days/month)
5. Severe central nervous system disease
6. Previous surgical or device closure of Patent Foramen Ovale (PFO)/Atrial Septal Defect (ASD)
7. Atrial heart valve
8. Pacemaker or Implantable Cardioverter Defibrillator (ICD) implanted within past three months
9. History of atrial fibrillation
10. Undergoing dialysis
11. New York Heart Association (NYHA) class three or four cardiac failure
12. Pregnant
13. Anticoagulation

Date of first enrolment

01/04/2007

Date of final enrolment

01/04/2008

Locations**Countries of recruitment**

Netherlands

Study participating centre

Leiden University Medical Centre (LUMC)

Leiden

Netherlands

2300 RC

Sponsor information**Organisation**

St Jude Medical Inc (Belgium)

Sponsor details

The Corporate Village

Da Vincilaan 11 - Box F1

Zaventem

Belgium

B-1935

Sponsor type

Industry

Website

<http://www.sjm.com/index.aspx>

ROR

<https://ror.org/04x0p4p48>

Funder(s)

Funder type

Industry

Funder Name

St Jude Medical Inc (Belgium)

Funder Name

Leiden University Medical Centre (LUMC) (The Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration