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

Submission date	Recruitment status	[ ] Prospectively registered
11/04/2007	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
11/04/2007	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
01/02/2019	Nervous System Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00369499

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
1. Mean values of monthly migraine periods
2. Quality of Life (QoL) using headache impact test questionaire

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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Not Specified

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes