STOP PAIN

No registrations found.

Ethical review	Not applicable
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22085

Source
Nationaal Trial Register

Brief title
STOP PAIN

Health condition

PFO, migraine, closure

Foramen ovale persistens, migraine, sluiting

Sponsors and support

Primary sponsor: St Jude Medical inc
The corporate village 11- box F1
B-1935 Zaventem
Belgium
0032 27746937
Coordinating clinical investigators: Prof MD Ferrari, Neurology department LUMC
Source(s) of monetary or material Support: fund=initiator=sponsor

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Mean values of monthly migraine periods
QoL using headache impact test questionaire.

Study description

Background summary

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.

Study objective

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.

Intervention

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

Contacts

Public
Leiden University Medical Center (LUMC), Department of Neurology
Postbus 9600
H. Koppen
Leiden 2300 RC
The Netherlands
h.koppen@lumc.nl
Scientific
Leiden University Medical Center (LUMC), Department of Neurology
Postbus 9600
H. Koppen
Leiden 2300 RC

The Netherlands
h.koppen@lumc.nl

Eligibility criteria

Inclusion criteria

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

Exclusion criteria

1. History of 15 or more headache days per month;
2. Taking preventive medication for other conditions other than migraine;
3. 8 or more non-migraine headache days/month;
4. Overuse of acute headache medication(use on 10 or more days/month;
5. Severe central nervous system disease
previous surgical or device closure of PFO/ASD;
6. Atrial heart valve;
7. Pacemaker or ICD implanted within past 3 months;
8. History of atrial fibrillation;
9. Undergoing dialysis;
10. NYHA class 3 or 4 cardiac failure;
11. Pregnant;
12. Anticoagulation

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Double blinded (masking used)

Control:	Placebo

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-04-2007
Enrollment:	50
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL893
NTR-old	NTR917
Other	:
ISRCTN	ISRCTN54702843

Study results