Pilot study Clip design
A pilot study about the first use of the Elana Clip design to create intracranial anastomoses

Published: 24-04-2014
Last updated: 23-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Nervous system, skull and spine therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON40251

Source
ToetsingOnline

Brief title
Pilot study Clip design

Condition

- Nervous system, skull and spine therapeutic procedures
- Aneurysms and artery dissections

Synonym
Intracranial giant aneurysm

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Clip, Pilot, sutureless

Outcome measures

Primary outcome

The primary endpoint of this pilot study is the technical success of the Clip system. A technical Clip system success is defined as follows:

1.The Clip has been used for graft to the recipient or donor vessel connection, without the need for any sutures and/or significant bleeding.

2. The laser catheter retrieved a tissue flap and after creation of the artheriotomy the connection area does not show significant bleeding that requires additional treatment.

3.No Clip system related serious adverse events are reported at the time the patient is leaving the OR

Secondary outcome

Due to the limited size of this pilot study no secondary endpoints will be defined. However basic information will be collected about:

• Creation of functional arteriotomy

• Total duration of surgery

• Need to use anticoagulation medication

• 7 days angiogram to verify patency (part of standard Elana procedure, so this is not an extra evaluation)

Study description

Background summary

In 2010 a pilot study was performed using the Elana Slide design. The breakthrough of this concept is that no sutures are required to create a connection between donor and recipient vessels (anastomosis). The huge advantage is that no sutures are required on vessels that run deep in the brain. To do this, space is required, which is barely available.Because of that, creating a suture in on vessels in the skull are very intensive and time consuming. With the Slide device, that requires no sutures, total operation time could be reduced and also even deeper structures (that are impossible to suture) could be reached.The slide pilot study was performed under protocol number NL32154.041.10. During this phase it appeared that the device was not optimal for further clinical use. Especially there was too much friction during the insertion into the recipient vessel and the visibility of positioning was limited. So a visual inspection during the operation was difficult.
The new Clip design overcomes the disadvantages of the Slide and has been tested extensively in vitro and in vivo (both rabbits and pigs). The results are very good and due to that the step towards a new human pilot study is justified. It will be a single site, single physican set up. The study set-up will be totally comparable to the previous Slide study.

Study objective

The objective of this pilot study is to investigate the feasibility of using the Clip system in a human setting in creating an intracranial arteriotomy in a non-occlusive, sutureless fashion. Although the focus is on the technical success of the design, at the same time the clinical success and the safety will be followed for 30 days to evaluate that no unexpected device related events occur

Study design

This is a pilot study. One surgeon within UMC Utrecht will perform all procedures. A maximum of 5 patients or a minimum of 5 device uses are targeted. (Note: in a patient both proximal and distal anastomoses could be created using the device)

Intervention

This is a pilot study and the intervention is exactly the same as that for the standard Elana technique. However instead of using a ring (that requires suturing) now the Clip device (sutureless) will be used.

Study burden and risks

By standard medical evaluation of a patient, outside any protocol, the physician will know if a patient requires an intracranial bypass operation and whether the ELANA procedure is indicated. When this is known, the patient will be asked to participate in this study. The whole medical treatment plan for the patient is not different and does not require any additional measures as compared to the standard ELANA procedure. So, as compared to the standard treatment there is no additional burden or risk for the patient.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patient is > 18 years old on the date he/she signed the informed consent ;Patient requires a temporary or permanent bypass in the brain as determined by the physician.;From preoperative considerations it seems that the patient can provide a suitable donor graft which does not seem to be varicose, obliterated or stenosed and which can be expected to have a diameter compatible with the proximal and distal target vessel with sufficient length to bridge the distance from the proximal to distal anastomosis;Target vessels should have an outer diameter of at least 3mm

Exclusion criteria

Patient cannot be without clopidogrel (Plavix®) for the surgery and through discharge ;Patient participates in another clinical investigation that could confound the evaluation of the Study device;Patient is allergic to Aspirin;Surgeon believes the patient is an unsuitable surgical candidate because of a poor general state of health, which would not permit the required operating and anesthesia time (add at an appropriate safety margin - at least 50% - to the expected surgery time in the assessment) or because of abnormal blood coagulation values

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2014
Enrollment:	5
Type:	Actual

Medical products/devices used

Generic name:	Clip design
Registration:	No

Ethics review

Approved WMO Date:	24-04-2014
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	27-08-2014
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	11-11-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	27-07-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	26-10-2016
Application type:	Amendment
Review commission:	METC NedMec

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
CCMO	NL45868.041.13

Study results

Results posted: 24-10-2020

Summary results
Trial ended prematurely

First publication
24-10-2020