Electromagnetic Stylet Post Market Clinical Followup Study

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Increased intracranial pressure and hydrocephalus
Study type	Observational non invasive

Summary

ID

NL-OMON50781

Source
ToetsingOnline

Brief title
EMS-PMCF

Condition

- Increased intracranial pressure and hydrocephalus

Synonym
Hydrocephalus, Normal-Pressure Hydrocephalus (NPH)

Research involving
Human

Sponsors and support

Primary sponsor: Brainlab A.G.
Source(s) of monetary or material Support: Brainlab A.G. financiert het onderzoek

Intervention

Keyword: Accuracy, Hydrocephalus, Neuronavigation, Shunt

Outcome measures

Primary outcome

The systematic investigation of prospective data obtained during clinical use of the EM Stylet will be performed by means of catheter placement evaluation on intraoperative or postoperative imaging (MRI or ultrasound).

Catheter placement accuracy will be assessed based on following grading system adapted from Hayhurst et al. (Hayhurst et al., 2010):

• Grade 1: Perforated catheter part is free floating in cerebrospinal fluid within the ventricle, approximately equidistant from ventricular walls, away from the choroid plexus and a straight trajectory from the burr hole.

• Grade 2: Perforated catheter part is attached to a ventricular wall or involves choroid plexus

• Grade 3: Perforated catheter part is partially or completely within the brain parenchyma or failed to cannulate the ventricle completely

Secondary outcome

Adverse events and Serious adverse events (all and device related)

Study description

Background summary

Placement of ventricular catheter is a well-established surgical procedure. Intracranial catheters are mostly supplied with a removable stiffening member, called a stylet. Stylets provide rigidity during insertion and can be removed so that the catheter is flexible post removal. However, these catheters do not have a means of navigation and are commonly placed with the freehand pass technique, which is associated with a high misplacement rate. The development of image-guided navigation systems have shown to substantially lower the rate of misplacement compared with the freehand pass technique. A successfully performed ventricular catheter placement (high tracking accuracy allows successful catheter placement) strongly points toward the absence of adverse events in the period after the procedure. The recently developed Brainlab EM Stylet is being used in clinical routine, but needs verification of accuracy and safety in a post-market clinical followup study. (PCMF)

Study objective

The aim of this PMCF study is to confirm the clinical safety and performance aspects of intracranial catheter placements for the medical indications, hydrocephalus of any origin or ICP elevation. The study design requires determination of catheter placement accuracy. As part of the treatment of hydrocephalus with intraventricular catheters, additional imaging for verification of the accurate placement of those catheters is a standard procedure for many adult and pediatric patients. This can either be done via MRI or ultrasound (the latter in the case of children younger than 12 months of age).

The study objectives are
1. Ventricular catheter location as assessed by intraoperative or postoperative imaging (CT or MR or ultrasound in children younger than 12 months of age) performed within 72h post-intervention. Catheter placement accuracy will be assessed based on the following grading system adapted from Hayhurst et al. (Hayhurst et al., 2010):
o Grade 1: catheter tip (perforated part) free floating in cerebrospinal fluid equidistant from ventricular walls, away from choroid and a straight trajectory from the burr hole.
o Grade 2: lateral catheter openings touching a ventricle wall or choroid
o Grade 3: catheter tip perforated part partially or completely within brain

parenchyma or failure to cannulate ventricle completely
2. Frequency and severity of adverse events and incidents are recorded as secondary outcome measures (secondary
endpoints) within the study period and will be collected by specific questioning and, as appropriate, by examination. Respective
information shall be recorded by the Investigator in the Case Report Form-Adverse Events (CRF-AE). The completed CRF-AE
shall be forwarded to the Sponsor within four weeks. SAEs, SADEs and device deficiencies that could have led to a SADE shall
be reported to the Sponsor without unjustified delay. Assessment and processing of the adverse events is performed by the
Sponsor.

Study design

This study design is considered appropriate to reach the study objectives.
The present PMCF study is a single center prospective non-randomized observational non-controlled single-arm trial to investigate whether
using the EM Cranial navigation system together with the EM stylet is as good as we think from prior clinical and pre-clinical studies.
Workflow:
• For a catheter placement, the Brainlab EM navigation system and Brainlab EM Stylet shall be used.
• The healthcare professionals will be responsible for the procedure(s) that the subjects undergo during surgery. This study
protocol does not contain a detailed description of the intervention that the subjects undergo during this investigation.
• An intraoperative scan or post-OP scan (MR or ultrasound for children younger than 12 months of age) of the catheter
location shall be performed. The post-OP scan shall take place within 72 hours post intervention.
• The anonymised mage data sets shall be uploaded to a secure platform (Quentry) within four weeks.
• All data shall be reviewed (e.g., by two blinded healthcare professionals grading the catheter tip placement according to the
protocol described in Hayhurst et al.).
• One CRF must be filled in for each enrolled patient who finishes the study:

o The CRF shall be completed within four weeks of performing the intraoperative or postoperative imaging.
o If applicable, the CRF-AE shall be submitted to the Sponsor within four weeks to record adverse events and incidents that occur during the procedure and in the period between device application and the post-operative scan, which must be performed
within 72 hours post-intervention. SAEs, SADEs and device deficiencies that could have led to a SADE event shall be reported
to the Sponsor without unjustified delay. For detailed information on adverse

events and handling, please refer to chapter 15 of this document.

Study burden and risks

The use of the device is according to clinical routine, as it is currently performed in our center. A subset of patients already receives postoperative imaging of the brain using MRI or ultrasound within 72 hours. We ask these patients for permission to use their data for analysis. The rest of the patients, that receive surgery using the EM-stylet but do not receive postoperative imaging within 72 hours we ask for permission to perform MRI or ultrasound imaging to assess catheter location. The burden and risk that is associated with participation is low. The data we collect on the accuracy and safety of the device can assist in the development of improvements to the device.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

• Male and female, all age groups
• Patient or legally authorized representative has signed the Informed Consent form
• Ventricular catheter placement for the indications:
o Elevated ICP
o Enlarged ventricles
o Disruption of the CSF drain of any origin
o Ventricular catheter placement for the placement of reservoirs (e.g., Ommaya).

Exclusion criteria

• Patients with slit ventricles (Frontal-Occipital Horn Width Ratio (FOHWR) <0.05)
• Very large ventricles (FOHWR >0.5)
• Patients with preexisting catheter path at the same access
• Exclusion criteria for MRI (e.g. pacemaker, recent prosthesis) judged by the treating physician

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2022
Enrollment:	134
Type:	Actual

Medical products/devices used

Generic name:	Brainlab Electromagnetic Disposable Stylet
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	13-10-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL76660.078.21