TachoSil® versus current practice in dura sealing techniques for the prevention of postoperative cerebrospinal fluid (CSF) leaks in patients undergoing skull base surgery: An open label, randomised, controlled, multicentre, parallel group efficacy and safety trial.

Published: 15-12-2009
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The objectives are to assess the efficacy and safety of TachoSil in sealing the dura mater to prevent postoperative CSF-leakage / clinically evident pseudomeningocele following skull base surgery, by comparison to current practice.

Ethical review	Approved WMO
Status	Pending
Health condition type	Skin and subcutaneous tissue therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON32695

Source
ToetsingOnline

Brief title
TASALL

Condition

- Skin and subcutaneous tissue therapeutic procedures

Synonym
Leakage of brain fluids.

Research involving
Human

Sponsors and support

Primary sponsor: Nycomed
Source(s) of monetary or material Support: Farmaceutische industrie

Intervention

Keyword: Dura sealing techniques, Skull base surgery, TachoSil

Outcome measures

Primary outcome

The primary endpoint is the occurrence of either a clinically evident CSF-leak

or a clinically evident pseudomeningocele.

Secondary outcome

The secondary endpoint is defined as the incidence of non-clinically evident

epidural fluid collections found on CT- or MRI-scans and will be evaluated

post-operatively until the Follow-up visit.

Study description

Background summary

Currently no unanimous consensus of how to seal the dura mater has been generally adopted as being the gold standard. TachoSil is currently registered for haemostasis, but is already being used for sealing the dura mater in neurosurgery. This trial has being set up to investigate the efficacy of TachoSil in the neurosurgery. As TachoSil is aimed to be introduced on the US market, the trial encompasses the need of a partially US based trial.

Study objective

The objectives are to assess the efficacy and safety of TachoSil in sealing the dura mater to prevent postoperative CSF-leakage / clinically evident pseudomeningocele following skull base surgery, by comparison to current

practice.

Study design

This is an open label, randomised, controlled, parallel-group, multicenter, phase III trial.

Intervention

Patients will be randomised for TachoSil or current practice.

Study burden and risks

Patients have 5 visits: screening, day of surgery, day 3, day of discharge and a follow-up visit.
At the screening visit, a complete blood investigation will be performed. In case of suspection of an infection, the physician can decide to have additional cultures of blood/cerebrospinal fluid/urine.
CT-/MRI-scan at screening and on day 3. If neccesary also at discharge and follow-up.
Chest X-ray if the physician suspects a lung infection.
3 x physical examination
3 x vital signs

TachoSil can have the following side-effects:
o Fever may occur commonly (less than 10%)
o Hypersensitivity or allergic reactions (which may include angioedema [rapid swelling of the skin], burning and stinging of the application site, bronchospasm [sudden constriction of the muscles in the walls of the vessels in the lungs], chills, flushing, generalised urticaria [skin rash], headache, hives, hypotension, lethargy, nausea, restlessness, tachycardia [heart rate that exceeds the normal range for a resting heart rate], tightness of the chest, tingling, vomiting, wheezing) may occur uncommonly (less than 1%). In isolated cases, these reactions may progress to severe anaphylaxis.
o Antibodies against components of product may occur rarely (less than 0.1%)
o Thromboembolic (blockage of blood flow) complications may occur if the preparation is unintentionally applied intra vascularly (inside blood vessels) (less than 0.01%)

Contacts

Public
Nycomed

Langebjerg 1
4000 Roskilde
DK
Scientific
Nycomed

Langebjerg 1
4000 Roskilde
DK

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Is the surgical approach/procedure consistent with skull base surgery? I.e. at least one of the following:
a. Lateral approach to the foramen magnum: far lateral, extreme lateral, anterolateral, posterolateral,
b. Approach to the jugular foramen: infratemporal, juxta condylar, transjugular,
c. Approach to the cerebello pontine (CP) angle and petrous apex retrosigmoïd, translabyrinthine, retrolabyrinthine, transcochlear (limited transpetrosal),
d. Approach to the middle fossa: subtemporal (+/- petrous apex drilling), pteronial approach (any fronto temporal approach +/- orbitozygomatic deposition),
e. Approach to the anterior fossa: subfrontal (uni or bilateral),
f. Approach to the midline posterior fossa.

Exclusion criteria

* Has the patient been subject to emergency surgery within the last 3 months i.e. all non-elective surgery?
* Is the patient expected to need additional neurosurgery within the follow-up periodof Week

7±1 at the same surgical site?
* Is the surgical approach/procedure consistent with any transcranial or transfacial or combination of transcranial - transfacial approaches with wide defect in the skull base? I.e. any of the following:
g. Trans basal approach,
h. Total petrosectomy,
i. Trans facial approach,
j. Trans sphenoïdal approach,
k. Endoscopic procedures,
l. Trans oral approach (and any extension: Le Fort, mandibulotomy).

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2011
Enrollment:	28
Type:	Anticipated

Ethics review

Approved WMO

Date:	15-12-2009
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO Date:	02-06-2010
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	23-12-2010
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	24-01-2012
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
EudraCT	EUCTR2009-013056-71-NL
CCMO	NL30063.091.09