A Randomized, Controlled Study to Evaluate the Safety and Effectiveness of EVICEL* as an Adjunct to Sutured Dural Repair

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To evaluate the safety and efficacy of EVICEL for use as an adjunct to dura sutures in elective cranial surgery to provide intraoperative watertight closure.

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

Summary

ID

NL-OMON36810

Source
ToetsingOnline

Brief title
The Evicel Adjunct to Sutured Dural Repair Study

Condition

- Skin and subcutaneous tissue therapeutic procedures

Synonym
CSF leakage; leakage of brain fluid

Research involving
Human

Sponsors and support

Primary sponsor: Omrix Biopharmaceuticals Ltd
Source(s) of monetary or material Support: OMRIX biopharmaceuticals Ltd.

Intervention

Keyword: CSF leakage, dural repair, elective craniotomy/craniectomy surgery, Fibrin sealants

Outcome measures

Primary outcome

The primary efficacy endpoint will be the proportion of success (intraoperative watertight closure) in the treatment of persistent intraoperative CSF leakage following primary suture repair. Intraoperative watertight closure will be defined as no CSF leakage from the dural repair intraoperatively following the randomly assigned treatment with EVICEL or control (additional dural sutures), as assessed during a Valsalva maneuver 20-25 cmH2O for 5-10 seconds).

The safety endpoints include:

- Incidence of CSF leakage within5 days (± 2) post-operatively.

- Incidence of CSF leakage within 30 days (± 3) post-operatively.

- Incidence of adverse events

- Incidence of surgical site infections (SSI) according to National Healthcare Safety Network (NHSN) criteria within 30 days (± 3) post-operatively.

Secondary outcome

not applicable

Study description

Background summary

A common complication of craniectomy or craniotomy is CSF leakage after sutured

dural closure.
In many cases (new) surgical intervention is required to treat this CSF leakage. By using Evicel as an adjunct to dura sutures in elective cranial surgery this can provide intraoperative watertight closure and CSF leakage can be prevented.

Study objective

To evaluate the safety and efficacy of EVICEL for use as an adjunct to dura sutures in elective cranial surgery to provide intraoperative watertight closure.

Study design

This is a randomized, multi-center controlled study evaluating the effectiveness of EVICEL* as an adjunct to sutured dural closure compared to control to obtain an intraoperative watertight dural closure.

Subjects will be randomized to either EVICEL Fibrin Sealant (Human) or to standard dural closure techniques using repair sutures only (control) in a 2:1 allocation ratio and will be stratified by surgical procedure, posterior fossa or supratentorial craniotomy.

Due to the nature of this treatment and indication this is an open-label study.

Subjects will be followed post-operatively through discharge and for 30 days (±3) post-surgery. The incidence of CSF leaks will be assessed within 5 days (± 2) and 30 days (±3) post-operatively as detected by any of the following: clinical observation, diagnostic testing or the need for surgical intervention to treat a CSF leak or pseudomeningocele.

Intervention

see above

Study burden and risks

Possible risks and discomforts that may be expected include any of the standard risks and discomforts associated with an elective surgical procedure.

In addition, when medicines are made from human blood, certain measures are put in place in their manufacturing process to prevent infections being passed on to patients. These include careful selection of blood donors to make sure those at risk of carrying infections are excluded, and testing of each donation for signs of virus or infections. The manufacturing process for Evicel includes steps that can inactivate or remove viruses. Despite these measures, when

medicines prepared from human blood are administered, the possibility of passing on infection cannot be totally excluded. This also applies to any unknown or emerging viruses or other types of infections.

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

Preoperative
1. Patient undergoing elective craniotomy/craniectomy for pathological processes in the posterior fossa (such as benign or malignant tumors, vascular malformation, and Chiari 1 malformations) or in the supratentorial region and who are demonstrated to have persistent CSF leakage following primary attempt at suture closure of the dural incision. After primary suture closure of the dural incision, CSF leakage will be evaluated during a Valsalva maneuver 20-25 cmH2O for 5-10 seconds.

2. Administration of perioperative antibiotic prophylaxis
3.Age >< = 18 yrs;Intraoperative
1. Surgical wound classification Class I (refer to Appendix II). Penetration of mastoid air cells during partial mastoidectomy is permitted.
2. The cuff of native dura along the craniotomy edge on each side is wide enough based on surgeon's judgment to facilitate suturing and to allow for sufficient surface area for adherence of the investigational product.

Exclusion criteria

Preoperative:
1. Subjects with a dura lesion from a recent surgery that still has the potential for CSF leakage.;Intraoperative:
1. Dura injury during craniotomy/craniectomy that cannot be eliminated by widening the craniotomy/craniectomy to recreate the native dura cuff.
2. Use of implants made of synthetic materials coming into direct contact with dura (e.g., PTFE patches, shunts, ventricular and subdural drains).
3. Planned use of dural onlay patches after primary suture closure of the dura.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-11-2010
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Evicel solutions for sealant
Generic name:	Evicel
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	23-03-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-05-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-09-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-02-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-03-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	EUCTR2009-016501-41-NL
CCMO	NL31260.029.10