MEDICAL UNIVERSITY OF WARSAW

Department of Neurosurgery
Head: Professor Andrzej Marchel, MD, PhD

Prophylactic Use of Dural Tenting Sutures in Elective Craniotomies – Is It Necessary? A multicenter Randomised Study.

STUDY PROTOCOL

14/01/2020

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1. Study Identification

Unique Protocol identification Number:

KB/106/2018

Brief Title:

Dural tenting sutures in neurosurgery - is it necessary?

Official Title:

Prophylactic use of dural tenting sutures in elective craniotomies - is it necessary? A multicentre randomised study.

Acronym:

Study Type:

Interventional

2. STUDY STATUS

Record Verification Date:

June 2018

Overall Recruitment Status:

Recruiting

Study Start Date:

September 7, 2018

Primary Completion Date:

Anticipated September 1, 2021

Study Completion Date:

Anticipated April 1, 2022

3. SPONSOR/COLLABORATORS

Responsible Party, by Official Title:

Sponsor

Investigator Information:

Investigator Name:

Przemysław Kunert

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Investigator Affiliation:

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Investigator Information:

Investigator Name:

Łukasz Przepiórka

Investigator Official Title:

Investigator Affiliation:

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Name of the Sponsor:

Medical University of Warsaw

4. OVERSIGHT

Studies a U.S. FDA-regulated Drug Product:

No

Studies a U.S. FDA-regulated Device Product:

No

Device Product Not Approved or Cleared by U.S. FDA:

No

Post Prior US FDA Approval or Clearance:

No

Investigational New Drug Application(IND)/Investigational Device Exemption (IDE) Information:

U.S. Food and Drug Administration IND or IDE:

No

Human Subjects Review:

Human Subjects Protection Review Board Status:

Submitted, approved

Board Approval Number:

KB / 106 / 2018

Board Name:

Komisja Bioetyczna przy Warszawskim Uniwersytecie Medycznym

(Bioetics Comitee, Medical University of Warsaw)

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Data Monitoring Committee:

Yes

FDA Regulated Intervention:

No

Section 801 Clinical Trial:

No

5. STUDY DESCRIPTION

Brief Summary (using lay language:)

This study evaluates the necessity of dural tenting sutures in craniotomies. The sutures elevate the dura, a layer between the brain and skull. Supposedly, by doing so, they prevent blood collecting between dura mater and the skull. These blood collections, called epidural hematomas, contributed greatly to postoperative mortality in the early days of neurosurgery. There have been several reports questioning the ongoing need for them in neurosurgery, thanks to modern hemostatic techniques. Moreover, it has been published in the literature, and is a common knowledge as well, that some neurosurgeons do not use these sutures at all, and do not have worse outcomes than their colleagues.

In this study, half of the randomly assigned participants will undergo craniotomy without dural tenting sutures and will be considered an intervention group. The other half will undergo craniotomy with these sutures.

Detailed Description:

In the early days of neurosurgery, epidural hemorrhages (EDH) contributed to a high mortality rate after craniotomies. Almost a century ago Walter Dandy reported dural tenting sutures as an effective way of preventing postoperative EDH. Over time, his technique gained in popularity and significance to finally become a neurosurgical standard.

Yet, there have been several retrospective reports questioning the ongoing need for dural tenting sutures. Dandy's explanation that the hemostasis under hypotensive conditions is deceiving and eventually causes EDH may be obsolete. These days, proper intra- and postoperative care, including maintenance of normovolemia and normotension and the use of modern hemostatic agents, may be enough for effective hemostasis. Evading of this suturing technique by some surgeons supports this argument even further.

Thus, there is a fundamental need to evaluate the necessity of dural tenting sutures in an unbiased, evidence-based manner.

6. CONDITIONS AND KEYWORDS

Primary Disease or Condition Being Studied in the Trial, or the Focus of the Study:

1. Epidural Hematoma

Keywords:

1. Craniotomy

2. Dural Tenting Suture

3. Epidural Hematoma

7. STUDY DESIGN (INTERVENTIONAL)

Primary purpose:

Prevention

Study Phase:

N/A

Interventional Study Model:

Parallel

Model Description:

We plan to include 2000 subjects in this study. Each subject will undergo a craniotomy for unrelated pathology. Each of the subjects will be assigned in random order to an intervention or control group. The intervention group will not have dural tenting sutures during closure of their craniotomy while the control group will have at least three.

Both groups will be followed radiologically and clinically, in the exact same manner.

Number of Arms:

2

Masking Roles, if Masking:

Participant

Investigator

Outcomes Assessor

Masking Description:

Due to the nature of the surgical procedures, the surgeon and the rest of the OR medical team will be aware of the current subject's allocation. However, in each case, the specific OR team aware of the subject's allocation will be different from the investigators performing further evaluation of the given subject. The following study procedures will be in place to ensure double-blind administration of the study.

- **Access to the randomization code will be strictly controlled.**
- **The surgeon will receive information on subject's allocation after commencing the surgery.**

The study blind will be broken:

1. **During interim monitoring, after recruiting the first 100 patients.**

2. **On completion of the clinical study and after the study database has been locked.**

3. **When patients' safety requires access to allocation data.**

Allocation:

Randomized

Enrollment Type:

Anticipated

Number of Participants:

2 000

8. ARMS, GROUPS, AND INTERVENTIONS

Arm 1:

Arm Type:

No intervention

Arm Title:

No dural tenting sutures

Arm Description:

No dural tenting techniques

Arm 2:

Arm Type:

Active Comparator

Arm Title:

Dural tenting sutures

Arm Description:

Dural tenting techniques

Intervention 1:

Intervention Type:

Procedure/Surgery

Intervention Name

No dural tenting techniques

Other Intervention Name 1:

No tack-up sutures

Other Intervention Name 2:

No hitch-up stitches

Intervention Description:

Not applying dural tenting sutures during closure of a craniotomy

Intervention 2:

Intervention Type:

Procedure/Surgery

Intervention Name

Dural tenting techniques

Other Intervention Name 1:

No tack-up sutures

Other Intervention Name 2:

No hitch-up stitches

Intervention Description:

Applying at least 3 dural tenting sutures during closure of a craniotomy in a usual way

Arm/Interventional Cross–Reference

	No dural tenting techniques	Dural tenting techniques
Experimental, no dural tenting sutures	☐	
Active comparator, dural tenting sutures		☐

9. OUTCOME MEASURES

Outcome 1:

Primary Outcome Measure:

Title:

Reoperation due to epidural hematoma

Description:

Percentage

Time Frame:

During hospitalization for the surgery, approximately 2 days postoperatively

Outcome 2:

Secondary Outcome Measure:

Title:

Postoperative 30-day mortality

Description:

Percentage

Time Frame:

30-day postoperatively

Outcome 3:

Secondary Outcome Measure:

Title:

Postoperative 30-day readmission to a neurosurgical or neurological department

Description:

Percentage

Time Frame:

30-day postoperatively

Outcome 4:

Secondary Outcome Measure:

Title:

New neurologic deficit or deterioration of a previous one

Description:

Specific description of a neurologic deficit

Time Frame:

During hospitalization, during hospitalisation, as evaluated 5–7 days postoperatively, or earlier if the patient is discharged before the fifth postsurgical day.

Outcome 5:

Secondary Outcome Measure:

Title:

Cerebrospinal fluid leak requiring treatment

Description:

Percentage

Time Frame:

During hospitalization, during hospitalisation, as evaluated 5–7 days postoperatively, or earlier if the patient is discharged before the fifth postsurgical day.

Outcome 6:

Secondary Outcome Measure:

Title:

Deterioration of postoperative headaches over 5 in Numerical Rating Scale

Description:

The Numeric Rating Scale is an 11-point scale for patient self-reporting of pain. It ranges from 0 (no pain) to 10 (the worst imaginable pain). There are no subscales. Higher values indicate more pain and, therefore, represent undesirable outcome.

Time Frame:

During hospitalization, during hospitalisation, as evaluated 5–7 days postoperatively, or earlier if

the patient is discharged before the fifth postsurgical day.

Outcome 7:

Secondary Outcome Measure:

Title:

Epidural collection thickness over 3 mm measured radiographically

Description:

The thickness of the epidural collection measured in a postoperative CT scan

Time Frame:

During hospitalization, approximately 1-3 days postoperatively

Outcome 8:

Secondary Outcome Measure:

Title:

Midline shift over 5 mm

Description:

Midline shift caused by the epidural collection measured in a postoperative CT scan

Time Frame:

During hospitalization, approximately 1-3 days postoperatively

10. ELIGIBILITY

Sex/Gender:

Sex:

All

Gender–Based:

No

Age Limits:

Minimum Age:

18

Unit of Time:

Years

Maximum Age:

75

Unit of Time:

Years

Accepts Healthy Volunteers:

No

Eligibility Criteria:

Inclusion Criteria:

- **Male or female over 18 an under 75 years old**
- **Qualified for an elective supratentorial craniotomy with a diameter of at least 3 cm**
- **Glasgow Coma Scale 15 preoperatively**
- **Modified Rankin Scale 0, 1 or 2 preoperatively**

Exclusion Criteria:

- **Coagulation abnormalities before the surgery**
- **Revision craniotomy**
- **Skull base surgery**

11. CONTACTS, LOCATIONS, AND INVESTIGATOR INFORMATION

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study principal investigator

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Official's Role:

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12. IPD SHARING STATEMENT

Plan to Share IPD:

No

IPD Sharing Plan Description

IPD Sharing Supporting Information Type:

IPD Sharing Time Frame:

IPD Sharing Access Criteria:

IPD Sharing URL:

13. REFERENCES

Citations

PubMed Identifier:

12617233

Citation

Swayne OB, Horner BM, Dorward NL. The hitch stitch: an obsolete neurosurgical technique? Br J Neurosurg. 2002 Dec;16(6):541-4; discussion 544.

Results Reference:

No

PubMed Identifier:

10433304

Citation

Winston KR. Efficacy of dural tenting sutures. J Neurosurg. 1999 Aug;91(2):180-4.

Results Reference:

No

PubMed Identifier:

9732254

Citation

Winston KR. Dural tenting sutures in pediatric neurosurgery. Pediatr Neurosurg. 1998 May;28(5):230-5.

Results Reference:

No

PubMed Identifier:

12617233

Citation

Swayne OB, Horner BM, Dorward NL. The hitch stitch: an obsolete neurosurgical technique? Br J Neurosurg. 2002 Dec;16(6):541-4; discussion 544.

Results Reference:

No

PubMed Identifier:

Citation

Wadanamby, S. et al., (2016). Is dural hitching necessary to prevent post-operative extradural haemorrhage in craniotomies and craniectomies. Sri Lanka Journal of Surgery. 34(2), pp.11-17. DOI: http://doi.org/10.4038/sljs.v34i2.8262

Results Reference:

No

Links

URL:

Description:

Available IPD and Supporting Information:

Available IPD/Information Type:

Available IPD/Information URL:

Available IPD/Information Identifier:

Available IPD/Information Comments: