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Identifying adjustable risk factors for wound healing problems in patients who have had autologous cranioplasty (reimplantation of the removed section of their skull) following decompressive hemicraniectomy (removal of a piece of skull to relieve pressure on the brain)

Submission date
02/10/2019

Recruitment status
No longer recruiting

Registration date
19/11/2019

Overall study status
Completed

Last Edited
14/01/2021

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Decompressive hemicraniectomy is a routine life-saving brain surgery. It involves cutting out a section of bone from the skull to release pressure caused by the brain swelling and pressing against the skull. Swelling can occur for a variety of reasons, including traumatic brain injury and stroke. Decompressive hemicraniectomy is used when other ways of reducing pressure inside the skull have failed or cannot be used. After the brain swelling has reduced, the bone flap (which has been stored frozen) should be reattached into the skull to restore normal appearance and brain protection. This procedure is called an autologous cranioplasty. Although this is a straightforward surgical procedure, there is a fairly high rate of infection or other problems, such as the bone flap breaking down or dying. If the bone flap does not heal back into the skull, it must be removed and a custom-made artificial implant is used to fill the hole. The aim of this study is to analyse medical records of people who have had this procedure as part of their normal treatment to identify if there are factors that contribute to cranioplasty failure, so that these can be adjusted in the future to reduce the complication rate.

Who can participate?
The records of all patients aged 16-90 years who had decompressive hemicraniectomy at Aachen University Hospital were examined and only those who also had autologous cranioplasty in 2010-2018 and had been followed up for at least 1 year were included. Children whose skulls were still growing were excluded.

What does the study involve?
The analysis was conducted on medical records of patients who had these procedures as part of normal treatment.

What are the possible benefits and risks of participating?
There are no benefits or risks of participating in the study because all patients received treatment as usual before the study was initiated.

Where is the study run from?
Aachen University Hospital (Germany)

When is the study starting and how long is it expected to run for?
October 2016 to December 2018

Who is funding the study?
Aachen University Hospital (Germany)

Who is the main contact?
Dr Michael Veldeman, mveldeman@ukaachen.de

Contact information

Type(s)
Scientific

Contact name
Dr Michael Veldeman

ORCID ID
https://orcid.org/0000-0003-3648-6842

Contact details
Pauwelstrasse 30
Aachen
Germany
52064
00492418035052
mveldeman@ukaachen.de

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
001

Study information

Scientific Title
Identifying adjustable risk factors for surgical site infection and aseptic bone resorption after autologous cranioplasty after decompressive hemicraniectomy

Acronym
post-DCH-aCP

Study objectives
We hope to identify surgery-specific risk factors and predictors of surgical site infection in patients after decompressive hemicraniectomy, for example operative time, timing of surgery (time between decompressive hemicraniectomy and cranioplasty), pre-cranioplasty laboratory results such as white blood cell count, and C-reactive protein (indicative for an ongoing infection) or incision type.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/04/2014, Ethics Committee of the Medical Faculty of Rheinisch-Westfälischen Technischen Hochschule Aachen [RWTH Aachen University] (Pauwelstrasse 30, 52074 Aachen, Germany; +49 241 80-89963; ekaachen@ukaachen.de), ref: EK 062/14

Study design
Retrospective cohort analysis

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Decompressive hemicraniectomy for the following diagnoses: malignant middle cerebral artery infarction, severe traumatic brain injury, subarachnoid hemorrhage or intracerebral hemorrhage.

Interventions
The intervention has been performed as a clinical decision independent of this observational retrospective analysis. Patients do not need additional examinations or interventions as part of this trial.
All patient underwent the implantation of their own cranial bone flap as part of routine medical practice in decompressive hemicraniectomy. All patients were routinely followed up as part of normal care. The post-surgical period of follow-up was at least 12 months. Patients who were lost to follow-up before the 12 months had passed were excluded.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Occurrence of surgical site infection, defined as a visible wound infection with or without dehiscence, or a positive spinal tap indication CSF infection requiring the removal of the implanted autologous bone flap. This was assessed by examining patients' medical records up to 8 years post-surgery. The minimal duration of follow-up for inclusion was 1 year.

Key secondary outcome(s))

Occurrence of aseptic bone resorption requiring the need for redo surgery and implantation of an allograft bone flap assessed by examining patients' medical records up to 8 years post-surgery. The minimal duration of follow-up for inclusion was 1 year.

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Aged 16-90 years at time of surgery
2. Treated using decompressive hemicraniectomy between 2010 and 2018 due to malignant stroke, traumatic brain injury, subarachnoid hemorrhage or intracerebral hemorrhage

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
186

Key exclusion criteria
1. Decompressive hemicraniectomy for other diagnoses i.e. infection, post-tumor surgery etc
2. Children with a growing skull (aged <16 years)
3. Immunosuppressed patients (including iatrogenic)

Date of first enrolment
01/01/2010

Date of final enrolment
31/12/2018

Locations

Countries of recruitment
Germany

Study participating centre
University Hospital Aachen
Pauwelstrasse 30
Aachen
Germany
52074

Sponsor information

Organisation
University Hospital Aachen [Universitätsklinikum Aachen]

ROR
https://ror.org/02gm5zw39

Funder(s)

Funder type
University/education

Funder Name
Medizinische Fakultät, RWTH Aachen University

Alternative Name(s)
Faculty of Medicine, RWTH Aachen University

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Germany

Results and Publications

Individual participant data (IPD) sharing plan
Anonymized data will be shared upon request to qualified researchers either by e-mail or by post.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	24/04/2020	14/01/2021	Yes	No