

# 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)

<b>Submission date</b> 02/10/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 19/11/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 14/01/2021	<b>Condition category</b> Surgery	<input type="checkbox"/> 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](mailto:mveldeman@ukaachen.de)

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**ClinicalTrials.gov (NCT)**  
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?
<a href="#">Results article</a>	results	24/04/2020	14/01/2021	Yes	No