PROTOCOL FOR AN OBSERVATIONAL STUDY

Enhanced Recovery Pathway for Chronic Subdural Hematoma

ERP-cSDH

Version number: v 2 **– Date** 1/09/2024

Internal ref. nbr: S68819

Sponsor

University Hospitals Leuven (UZ Leuven)

Herestraat 49, B-3000 Leuven

LIST OF PARTICIPATING SITES

List Of Participating Sites

UZ Leuven, Herestraat 49, 3000 Leuven

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FUNDING AND SUPPORT

Funder	Type of Financial or Non-Financial Support
Departement of Neurosurgery, UZ Leuven	Financial support for study set-up, data management program and statistical support

ROLES AND RESPONSIBILITIES

The Principal Investigator (PI) is responsible for the conduct of the Study at his/her Participating Site, and for protecting the rights, safety and well-being of Study participants. As such the PI must ensure adequate supervision of the Study conduct at the Participating Site. If any tasks are delegated, the PI will maintain a log of appropriately qualified persons to whom he/she has delegated specified Study-related duties. The PI will ensure that adequate training is provided and documented for all Study staff, prior to conducting assigned Study-related activities. Even when certain activities are delegated, the PI will ultimately remain responsible for the conduct of the Study at his/her Participating Site.

It is the Coordinating Investigator's (CI's) responsibility to supervise the general conduct (e.g. Study progress, communication, protocol training and support of the participating sites, annual reporting to the Ethics Committee (EC), end of Study notification(s) and results reporting…) of the Study. The CI fulfils both Investigator and Sponsor responsibilities, as outlined in International Conference on Harmonisation – Good Clinical Practice (ICH-GCP) E6(R2) and applicable regulations.

PI and CI shall each be referred to as «Investigator(s)».

STUDY SYNOPSIS

Title of clinical Study («Study»)	Enhanced Recovery Pathway for Chronic Subdural Hematoma
Protocol Short Title Acronym	ERP-cSDH
Sponsor name	University Hospitals Leuven (UZ Leuven)>
Medical condition or disease under investigation	Chronic subdural hematoma
Study rationale	A chronic subdural hematoma (cSDH) is a type of intracranial hematoma that primarily affects older adults. The rising incidence of this condition, coupled with the high healthcare burden of this disease, calls for an update of the medical care program. We introduced an enhanced recovery protocol (ERP) at our center for patients undergoing treatment for a chronic subdural hematoma. Our ERP includes guidelines for treatment decisions (surgery or middle meningeal artery embolization - MMA), modifications in surgical techniques, and standardized postoperative management strategies. Prospective analysis of the treatment outcomes is vital.
Primary objective	Analysing the safety and efficacy of an enhanced recovery protocol for patients undergoing burr hole drainage of a chronic subdural hematoma. Safety and efficacy outcomes will be compared with the outcomes of a historical patient cohort. Safety of the protocol will be measured in terms of recurrence rate (primary outcome, non-inferiority analysis), complication incidence, and 30-day mortality. Efficacy of the enhanced recovery protocol will be represented by the length-of-stay.
Secondary objective(s)	A separate analysis will be performed measuring the difference in treatment related costs between the historic treatment protocol and the enhanced recovery protocol.
Trial Design	Non-interventional, prospective, non-inferiority trial
Sample size	Prospective patient cohort: 150 subjects Retrospective patient cohort: all eligible consecutive patients treated by burr hole drainage between 2012-2022
Maximum duration a research subject remains in the study	6 months
Participating research sites	University Hospitals Leuven (UZ Leuven)
Third parties	None

1. Background and Rationale

Briefly explain the background, issues and medical relevance of the study. Make a convincing case as to why the study would create valuable and useful scientific knowledge, what the expected benefits and risks are, and the rationale as to why it is expected that this Study will have a positive benefit/risk balance.

A chronic subdural hematoma (cSDH) is a type of intracranial hematoma that occurs mainly in older adults, and which is pathogenically characterized by the slow accumulation of blood between the cerebral cortex and the dura mater. Clinical manifestations of a cSDH vary depending on the size of the hematoma and the extent to which it compresses different parts of the brain, although common features include headache, limb weakness, mental disorders, and epilepsy. The process of cSDH formation and progression remains poorly understood, and possible explanatory hypotheses include subclinical brain injury causing bridging vein trauma, inflammatory responses, transformation of an acute subdural hematoma, osmotic pressure gaps, and neovascularization of leaky vessels in the subdural membrane.[1] At present, the most common treatment strategy for a cSDH involves surgical drainage of the hematoma, although lately endovascular treatment is gaining popularity. Endovascular embolization of the middle meningeal artery (MMA) impedes neovascularisation of highly permeable dural vessels and has been shown to reduce hematoma volume.[2] The exact part of this novel treatment modality in the treatment of cSDH patients remains rather uncertain.

The estimated yearly incidence of CSH ranges from 8.2 to 20.6 per 100.000, but in the age group over 65 this rises to 58 per 100 000 per year, which makes it one of the most prevalent neurosurgical conditions.[3, 4] The burden of cSDH is even projected to increase in the decades ahead due to the growing elderly population and the widespread use of antithrombotic agents, which are believed to promote hematoma formation.[5, 6] A cSDH has been described as a 'sentinel health event' indicating underlying systemic pathology, because it has a 1-year mortality similar to that of hip fractures.[7]

There are still major challenges in cSDH treatment. The risk of recurrence after treatment is high. Hematoma recurrence causes repeated intervention, leading to prolonged hospital stays, higher morbidity, mortality, and healthcare costs.[8] In the literature, the recurrence ratio ranges from 3 to 33%.[9-11] In UZ Leuven, there were 13 cases of recurrence on 119 procedures (10,9%) that were performed in the adult population between 01-01-2019 and 31-08-2022. Other challenges are the lack of sufficient class I evidence describing the optimal surgical and perioperative management, overload of conflicting evidence concerning treatment, uncertainty of optimal antithrombotic withdrawal interval and lack of multidisciplinary healthcare pathways in the elderly.[12]

The increasing incidence of this pathology together with its high healthcare burden calls for an update of the medical care program in order to decrease disease-related morbidity and costs. We introduced an enhanced recovery program (ERP) in our centre for patients undergoing surgery for a chronic subdural hematoma. An ERP can be defined as a series of evidence-based practices covering all aspects of perioperative care, serving to minimize the patients' surgical stress response, facilitate recovery and decrease complication incidence.

Elderly patients stand to benefit from minimally invasive treatments given their advanced age and subsequent increased rate of comorbidities and surgical risk factors. An integrated approach to care in patients with a cSDH, similar to care of fragility fractures in the elderly, may be an important strategy to improve patient care and outcomes.[7] Our ERP-care pathway comprises of treatment decision guidelines (surgery and/or MMA), changes in surgical techniques and standardized postoperative management strategies.

2. Study Objectives and Design

2.1 Study objectives

State the purpose of the study (i.e. aims and objectives). Describe the primary research question, and define a specific hypothesis. See also:
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002877.pdf

The primary aim of this study is to evaluate the efficacy and safety of our ERP in patients undergoing surgical drainage of a chronic subdural hematoma. We hypothesize that the implementation of an enhanced recovery pathway will result to a lower in-hospital complication incidence and length of stay without increasing hematoma recurrence rate.

Secondary aim:

A separate analysis will be performed measuring the difference in treatment related costs between the historic treatment protocol and the enhanced recovery protocol.

2.2 Primary Endpoints

Define specific parameters that will be assessed to achieve the primary objective (i.e. specific hypothesis) of the study. These are the datapoints that will be collected in the study-specific Case Report Form (CRF).

The primary outcome will be recurrence rate assessed at 6 months after index surgery. Recurrence is defined as persistent deficits, clinical deterioration or radiographic hematoma enlargement requiring ipsilateral re-intervention (surgical or by means of MMA). In case of bilateral hematomas, a unilateral recurrence would suffice to be recorded as a recurrence. A second recurrence will not be included in the analysis.

2.3 Secondary Endpoints

Define parameters that will be assessed. These are the datapoints that will be collected in the study-specific Case Report Form (CRF).

Secondary outcomes are:

- Length of stay (LOS) after surgery

- Complication incidence. Complications will be classified as medical complications (any nonsurgical complication occurring during the hospital stay after the surgery) and surgical complications. Medical complications are considered minor if complete recovery is to be expected (eg, electrolyte disturbances or urinary tract infection) and major in case of potential serious consequences and partial or no recovery (eg, stroke, severe pneumonia, or pulmonary embolism). Surgical complications are defined as every complication directly related to the surgery. Epileptic seizures in the postoperative period will be considered separately.

- Total costs of hospital admission

- 30-day mortality

2.4 Study Design

Describe the design of the research study.

We will conduct a single-centre, prospective, non-interventional cohort study in patients treated for a chronic subdural hematoma at University Hospitals Leuven (Belgium). An enhanced recovery pathway (ERP) for chronic subdural hematoma patients was developed in conjunction with the department of neuroanaesthesiology and neurosurgery. The ERP is gradually being implemented as new standard of care. The ERP consists of guidelines for treatment modality (surgery or MMA), modifications in surgical techniques, and standardized postoperative management strategies (cfr. Supplemental content). All consecutive patients with a chronic subdural hematoma requiring burr hole evacuation will be included for analysis. Study participants with bilateral cSDH will be included as a single study participant.

For the primary analysissafety, efficacy, and costs outcomes of patients treated with burr hole drainage after ERP-implementation will be compared with outcomes of a historic cohort of the pre-ERP era. This historic cohort will retrospectively be assessed and comprises of all consecutive adult patients who underwent burr hole drainage between January 2012 and December 2022. In this timeframe, treatment regime for cSDH patients was not subjected to change. The patient data of the historic cohort will be extracted from electronic patient files. Patients treated during the transition period (January 2023 to September 2024) will be neglected for analysis. Safety outcomes comprise of recurrence rate (primary outcome), complication incidence and 30-day mortality. Efficacy of the protocol will be measured through length-of stay. Non-inferiority of the ERP-protocol in comparison to the historic cohort will be analysed for the primary outcome.

Outcome data for our prospective cohort will clinically be assessed at hospital discharge, clinically and radiologically at 4-6 weeks and clinically 6 ± 1 months after treatment. Furthermore, an EQ-5D-5L questionnaire will be provided at baseline and at 6 ± 1 months after treatment. At 6 ± 1 months after treatment a short satisfaction survey will also be added. These questionnaire will be provided through the secure environment of nexuzhealth (through the app, quest on tab, on paper or through a safe link in an email). Reminders will be programmed and sent out if questionnaires are not completed. A baseline questionnaire will be filled in by the patient or by the relatives at the moment of the informed consent and inclusion in the study.

Trial flowchart

	Screening	Baseline	Intervention (surgery/MMA)	Hospital discharge	FU clinical (4-6 weeks; SoC)	FU clinical (6 ± 1 months ; SoC)
Check in-and exclusion criteria	x					
Informed consent		x				
Demographic data		x				

Neurological status (NIHSS, mRS, Markwalder score[13]), seizures, antitrombotic medication use		x			x	x
Hematoma characteristics on CT-imaging		x			x	
Intraoperative variables (operation duration, uni-or bilateral surgery, catheterisation technique and material)			x			
Duration of catheter presence, length of stay, hospital costs				x		
Readmissions, 30-day mortality, complications, and seizures					x	x
PROM's (EQ-5D-5L)		x				x

2.5 Expected duration of the study

Specify the expected duration and define the end of the study for the study participants. This can be the full study duration e.g. first patient first visit to last patient last visit including follow up. Alternatively, for long running studies (e.g. oncology), the end of study can be defined at a specific time point at which the study will be regarded as completed even if participants are still in follow up. A simple table format or timeline is the preferred style. Make the distinction between the expected overall study duration for the research site(s) and the expected study duration for a single participant..

Patients can be included in the trial as soon as surgery is scheduled. Study will end after the clinical follow-up at 6 ± 1 months after intervention.

2. Study Population / Eligibility Criteria

3.1 Inclusion criteria

List details under which a participant is considered eligible for inclusion in the study.

Participants eligible for inclusion in this study must meet all of the following criteria:

1. Age 18 years or older
2. Existence of a chronic subdural hematoma requiring burr hole drainage
3. Written informed consent to participate in the study must be obtained from the subject. If the subject is not capable of self-consent, all efforts will be made to locate a legally acceptable representative to act on behalf of the subject. When the patient is considered capable to consent but physically unable to sign an informed consent form and a representative is not available an impartial witness can attend the informed consent process.

3.2 Exclusion criteria

List details under which a participant is considered unsuitable for inclusion in the study

Participants eligible for this study must not meet any of the following criteria:

1. Acute subdural hematoma
2. Existence of an important underlying cerebral lesion (e.g. a vascular lesion)
3. History of treatment (surgical or by MMA) of a same sided cSDH

4. Assessment of Efficacy

Describe the measures that will be used to determine the efficacy of treatment (eg glucose, blood pressure, tumour reduction etc). Primary efficacy parameters should be stated first, then any secondary parameters (may already have been described in the study design)

The efficacy of an enhanced recovery pathway can be assessed either by analysing pathology-specific outcomes measures or by outcome measures related to the efficacy of the care pathway. Efficacy assessment will be performed by comparing recurrence rate, complication incidence, 30-day mortality and length-of stay of the ERP-cohort with the pre-ERP cohort.

5. Assessment of Safety

Describe the measures that will be used to determine subject safety during the study. These will include physical examination, blood tests and adverse event reporting

5.1 Specification, timing and recording of safety parameters

Adverse events are defined as any undesirable experience occurring to a subject during the study, whether or not considered related to the treatment pathway. During hospitalisation, daily clinical examinations will be performed as part of standard of care to assess patient status. To assess safety of our new care pathway complications (surgical and medical complications), 30-day mortality rate and hematoma recurrence will be strictly monitored. No interim analyses are scheduled.

Since this is a non-interventional observational study comparing a new standard of care with a historic treatment strategy, inclusion in this study does not impose any patient's risk.

5.2 Treatment stopping rules

This study evaluates the effectiveness and safety of an ERP for chronic subdural hematoma patients. Protocol deviation will be noted but does not lead to subject withdrawal. All patients will be invited to complete the 6-month questionnaires unless patient deceased.

6. Statistics and Data Analysis

Clearly define the study hypotheses which will be the object of statistical testing, and provide comprehensive outcome definitions. If no detailed Statistical Analysis Plan (SAP) will be developed, than provide a detailed description of statistical principles (e.g. justification of sample size, confidence levels and p-values, handling of protocol deviations and incomplete data, analysis methods, which software will be used, etc.)

The hypothesis of the study is that implementation of an ERP for chronic subdural hematoma patients leads to fewer complications, shorter length-of stay and cost-reduction without increasing hematoma recurrence rate.

We hypothesize that we can include about 150 patients in our study over a 3-year study period. With a one-sided alpha of 0.05, a non-inferiority margin of 10% and an expected primary endpoint rate (recurrence rate) of 11%, we can reach a calculated power of 60%. The final power of the study will be higher due to a larger pre-ERP patient cohort (retrospective analysed over a 10-year period) and because correction for baseline variables will be performed (cfr. infra). A non-inferiority margin of 10% seems to be justified, because: 1) the recurrence rate in our hospital is already low according to recurrences rates mentioned in literature, 2) an increase of recurrence rate of 10% will be justified if effectiveness of the ERP can be proven in terms of complication incidence, mortality and costs, and 3) with the upcoming usage of adjuvant embolization (= treatment by burr hole evacuation followed by prophylactic endovascular embolization in cases with an assumed high risk of recurrence) actual recurrence rates are likely to be lower than in the historic patient cohort, in which embolization was not routinely performed.

Descriptive statistics will be used to summarize patient baseline characteristics for both patient cohorts and baseline imbalance will be analysed. Percentages will be used for categorical variables and means and standard deviations or medians and interquartile ranges, when appropriate, for continuous variables. The primary endpoint will be compared between the ERP-cohort and pre-ERP-cohort using logistic regression for frequency comparison. Secondary endpoints will be analysed using appropriate statistics. Categorical data will be compared using X^2 test or Fisher's exact test. Numerical data will be analysed with the student's t test (for normally distributed continuous variables), Mann-Whitney U test (for non-normally distributed continuous variables) or the Fisher's exact (for categorical data).. Analyses will be adjusted for baseline patient characteristics that are associated with the outcome: Markwalder score, hematoma thickness, age and antitrombotic use. Logistic regression will be used for adjustments when appropriate. Multiple imputation will be performed is there is substantial missing data. Statistica® will be used for statistical analysis. Statistical significance will be established at p less than 0.05. All available data will be used. No data imputation will be performed.

7. Data handling

7.1 General data handling information

Data collection, handling, processing and transfer for the purpose of this Study will be performed in compliance with applicable regulations, guidelines for clinical studies and internal procedures. It remains the responsibility of the Investigator to check that all data relating to the Study, as specified in the Study protocol, are entered into the electronic Case Report Form ((e)CRF) in accordance with the instructions provided and that the forms are filled out accurately, completely and in a timely manner.

(e)CRFs are provided by the Sponsor for each participant. The Study data will be transcribed from the source records into an (e)CRF by Study Staff.

The (e)CRFs shall under no circumstances capture personal data such as but not limited to the participant or their relative(s) name, home address, contact details, full date of birth, medical record number (e.g. UZ Leuven EAD number), social security number etc.

Transfer of the pseudonymized data will be performed via a secured method of transfer taking into account all applicable security arrangements and regulations (such as the European General Data Protection Regulation). The receiving party will be bound by contractual agreement to keep the transferred data confidential at all times and to only process the data for the purpose of the Study. To this end, appropriate Data Transfer Agreements (DTAs) will be established.

7.2

Provide details of electronic CRF that will be used, describe the database and specify what kind of data will be collected

REDcap will be used to capture study related data.

The following data will be collected in the (e)CRF :

- Demographic data:
  - Age
  - Gender
- Baseline data
  - NIHSS score
  - mRS (modified Rankin Scale)
  - Markwalder score
  - Antithrombotic agents use and indication.
  - History of recent head trauma
  - Radiographic characteristics: hematoma side, uni-or bilateral hematoma, hematoma thickness, hematoma volume, amount of midlineshift, predominant hematoma density (hypodens, isodens, hyperdense or membranous)
  - Risk of falling (> 1 per month)
  - Excessive alcohol use
  - Cerebral atrophy
  - EQ-5D-5L
- Treatment variables
  - Type of anesthaesia (general, local, local with sedations)
  - Duration of operation
  - Uni-or bilateral surgery
  - Number of burr holes
  - Catheterisation technique (subdural vs subperiostal)
  - Drainage system (Jackson-Pratt vs conventional Codman collector system)
  - Embolisation technique
  - Embolization device
- Timing
  - Date of admission
  - Date of IC
  - Length of stay
  - Date of treatment
  - Date of discharge
  - Date of clinical follow-ups
  - Date of end-of-trial (EOT) + cause of EOT
- Costs of hospitalisation

- Restart time of antithrombotic agent
- All medical and surgical complications
- Seizures
- Postoperative NIHSS and mRS (assessed at 4-6 w and 6 ± 1 months postintervention)
- Postoperative hematoma volume and thickness
- Readmission + date
- 30-day mortality
- EQ-5D-5L at 6-month

7.3 Direct Data Access

Please specify or make reference to another written agreement) that the investigator(s) and the institution(s) will permit trial-related monitoring, audits, EC review, and regulatory inspections (where appropriate) by providing direct access to source data and other documents (i.e. patients' case sheets, blood test reports, X-ray reports, histology reports etc).

The Investigator will make source data and documents for this study available to an appropriately qualified quality assurance auditor mandated by the CTC, ethical committee and to regulatory authority inspectors, after appropriate notification.

8. Ethical and Regulatory Considerations

8.1 Ethics Committee (EC) review & reports

Before the start of the Study, this protocol and other related documents will be submitted for review to the EC for Study authorization. The Study shall not commence until such approvals have been obtained and until other relevant essential Study documents, such as duly signed contract agreements, evidence of adequate Study financing etc. are in place.

8.2 Protocol / GCP compliance

The Study must be performed in accordance with the protocol, current ICH and ICH-GCP guidelines, and applicable regulatory and country-specific requirements. ICH guidelines are an international ethical and scientific quality standard for designing, conducting, recording, and reporting studies that involve the participation of human participants. Compliance with this standard provides public assurance that the rights, safety, and well-being of Study participants are protected, consistent with the principles that originated in the most recent version of the Declaration of Helsinki, and that the Study data are credible, reliable and reproducible.

8.3 Data protection and participant confidentiality

The Study will be conducted in compliance with the requirements of the EU General Data Protection Regulation 2016/679 (GDPR), and the relevant Belgian laws implementing the GDPR including the Belgian Privacy Act of 30 July 2018 on the protection of privacy in relation to the processing of personal data. Any collection, processing and disclosure of personal data, such as participant health and medical information is subject to compliance with the aforementioned personal data protection laws (cfr. Data Processing Annex (DPA) in Appendix). In case personal data is transferred outside the European Economic Area, safeguards will be taken by the Sponsor to ensure that appropriate protection travels with the data in accordance with the GDPR. (https://ec.europa.eu/info/law/law-topic/data-protection/international-dimension-data-protection/rules-international-data-transfers_en#documents)

Any personal data shall be treated as confidential at all times including during collection, handling and use or processing, and the personal data (including in any electronic format) shall be stored securely at all times and with all technical and organizational security measures that would be necessary for compliance with EU and national data protection legislation (whichever is more stringent). The Sponsor shall take appropriate measures to ensure the security of all personal data and guard against unauthorized access thereto or disclosure thereof or loss or destruction while in its custody.

9. Research Registration, Dissemination of Results and Publication Policy

The Declaration of Helsinki (latest version) and European and Belgian regulations require that every research Study involving human participants be registered in a publicly accessible database before recruitment of the first participant. The CI is responsible for registering the Study.

In addition, the CI will fulfil their ethical obligation to disseminate and make the research results publicly available. As such the CI is accountable for the timeliness, completeness and accuracy of the reports. Researchers, authors, Sponsors, editors and publishers must adhere to accepted guidelines for ethical reporting. Negative and inconclusive, as well as positive results must be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest must be declared in publication.

ℹ The below section can be revised provided that compliance with ethical principles is maintained

Publications will be coordinated by the CI. Authorship to publications will be determined in accordance with the requirements published by the International Committee of Medical Journal Editors and in accordance with the requirements of the respective medical journal.

For multicentre Studies, it is anticipated that the primary results of the overall Study shall be published in a multicentre publication.

Participating Sites are not allowed to publish any subset data or results from the Study prior to such multicentre publication.

Any publication by a Participating Site must be submitted to the Sponsor for review at least thirty (30) calendar days prior to submission or disclosure. Sponsor shall have the right to delay the projected publication for a period of up to three (3) months from the date of first submission to the Sponsor in order to enable the Sponsor to take steps to protect its intellectual property rights and know-how.

10. Insurance/Indemnity

In accordance with the Belgian Law relating to experiments on human persons dated May 7, 2004, Sponsor shall assume, even without fault, the responsibility of any damages incurred by a Study Patient and linked directly or indirectly to the participation to the Study, and shall provide compensation therefore through its insurance.

11. References

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12. Supplemental Content

Summery overview of pre-ERP and ERP care elements

	Pre-ERP	**ERP**
Treatment modality		
Surgical treatment modality	Mostly burr hole drainage	Preferably burr hole drainage, craniotomy only when deemed necessary according to treating neurosurgeon based on clinical or radiographic factors.
Adjuvant embolization of the middle meningeal artery	Not routinely performed	In cases with assumed high risk of reccurence (use of anticoagulants, severe brain atrophy, high fall risk, ethanol abuse …) adjuvant (prophylactic) emobilization can be performed.
Anaesthesia		
Anaesthesia	Mostly combination of general and local anaesthesia	Local anaesthesia with sedation when possible.
Surgical technique		
Number of burr holes	2	1
Irrigation	Irrigation performed	Irrigation with fluid at body temperature performed
Catheterisation technique	Subdural drainage	Subgaleal drainage
Catheterisation material	Codman® External Drainage System	A Jackson-Pratt drainage system
Postoperative management		
Mobilisation	48h bedrest	Immediate mobilisation with physiotherapist or nurse.

Duration of drainage	48h	At least 24u
Postoperative imaging	At 2 days postoperative	Only at indication
Discharge	At discretion of neurosurgeon	At discretion of neurosurgeon
Restart of anticoagulants/antithrombotic	At discretion of neurosurgeon	At discretion of neurosurgeon
Follow-up	Clinical follow-up at 4-6 weeks postoperative, with CT-scan	Clinical follow-up at 4-6 weeks postoperative, with CT-scan, and clinical follow-up at 6 months