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Using ultrasound to monitor brain pressure during sinus surgery

Submission date
14/07/2025

Recruitment status
No longer recruiting

Registration date
16/07/2025

Overall study status
Completed

Last Edited
16/07/2025

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Functional endoscopic sinus surgery (FESS) is a minimally invasive surgical technique primarily indicated for the treatment of chronic rhinosinusitis. The technical advancement of surgical instruments and optics has expanded these indications to include pituitary tumors, skull base defects, sinonasal tumors, and complications of acute rhinosinusitis. During the performance of FESS, the entire surgical field is endoscopically irrigated with large amounts of saline solution. Given the very complex anatomy and surrounding structures that border the area of interest during the execution of FESS, there is a risk, albeit rare, of complications and damage to the relevant structures. Complications may include bleeding (epistaxis), infection, injury to the orbit, injury to the base of the skull, leakage of cerebrospinal fluid, and a recurrence of the underlying disease. Therefore, researchers have proposed that FESS may influence changes in intracranial pressure (ICP), a possibility that has not been described in the world literature. Increased intracranial pressure is a potentially life-threatening condition that can lead to impaired brain perfusion, especially in older individuals with disrupted cerebral autoregulation, and it can result in brain ischemia if elevated intracranial pressure persists or is not treated. Ultrasound of the eye can be useful in diagnosing many conditions, including retinal detachment, foreign bodies, lens dislocation, vitreous hemorrhage, and other surface abnormalities that can cause vision loss. Also, measuring the optic nerve sheath diameter (ONSD) can be used in cases of suspected or confirmed traumatic brain injury, intracranial hypertension, or optic neuritis. Bedside ocular ultrasound is a non-invasive examination that avoids the risk of infection, bleeding, or ionizing radiation, which are inevitable with the use of standard intracranial monitoring methods and computed tomography. This study aims to prove that FESS can lead to changes and an increase in intracranial pressure (ICP), which will be quantitatively verified through non-invasive ultrasound measurement of the ONSD.

Who can participate?
Patients over the age of 18, of all genders, who are scheduled for elective FESS

What does the study involve?
All patients will receive the same general anesthesia during surgery. The process will begin with a small dose of a strong painkiller (sufentanil) and a continuous infusion of a sleep-inducing drug (propofol), which will be carefully adjusted using a monitor that tracks brain activity to ensure

the patient stays safely asleep. A muscle relaxant (rocuronium) will be used to help with placing the breathing tube and to keep the body still during the operation. Throughout the surgery, anesthesia will be maintained using propofol alone, with continuous monitoring to keep the depth of sleep within a safe range. After the procedure, pain relief will be provided using paracetamol and anti-inflammatory medications like ibuprofen.

To estimate brain pressure during surgery, an ultrasound scan of the eyes will be performed using a specialized machine. One trained examiner will carry out all measurements to ensure consistency. The scan will be done with the patient lying down and eyes closed, and measurements will be taken from both eyes in two directions. The average of these measurements will be used to assess brain pressure. This will be done at four key points: before anesthesia is given, right after anesthesia but before surgery starts, at the end of surgery, and after the patient wakes up but before they are moved to recovery.

What are the possible benefits and risks of participating?
The conducted research would significantly clarify the behavior of the value of ICP during FESS. This would contribute to patient safety, better treatment, and the prevention of potentially dangerous complications. It is hoped that this research will improve the protocols for standardized anesthesiological monitoring of patients during the execution of this type of procedure in our center and possibly worldwide.

The patient's risk does not change by participating in this research. The research itself does not affect patients' health. Additionally, standard diagnostic, therapeutic, or surgical protocols will not change during this research.

Where is the study run from?
Clinical Hospital Centre Rijeka, Croatia

When is the study starting and how long is it expected to run for?
September 2024 to August 2025

Who is funding the study?
Clinical Hospital Centre Rijeka, Croatia

Who is the main contact?
Katarina Tomulić Brusich, ktomulic@gmail.com and katarinatb@medri.uniri.hr (The University of Rijeka, Faculty of Medicine, Croatia)

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Evaluation of intracranial pressure during functional endoscopic sinus surgery using ultrasound measurement of the optic nerve sheath diameter

Acronym
FESS-ONSD

Study objectives
Functional endoscopic sinus surgery (FESS) can cause changes and raise intracranial pressure (ICP), which will be measured using a non-invasive ultrasound to check the size of the optic nerve sheath (ONSD).

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 14/02/2025, Clinical Hospital Centre Rijeka- Ethics Committee (Krešimirova 42, Rijeka, 51000, Croatia; +38551658808; Kristina.Vucinic@kbc-rijeka.hr), ref: 003-05/24-01/147

Study design
Single-centre prospective cross-sectional observational study

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Observation of optic nerve sheath diameter as an indirect, non-invasive measurement of elevated intracranial pressure during functional endoscopic sinus surgery.

Interventions
The patients were thoroughly informed about the study by the principal investigator or collaborators in the preoperative room during preparation for the surgical procedure. If the patients decided to participate, Informed Consent was obtained.

General anesthesia will be standardized for all patients. The introduction to anesthesia will be carried out using a bolus administration of sufentanyl (0.4-0.5 mcg/kg) along with a continuous infusion of propofol via an infusion pump, the TCI model (target control infusion), Schneider's model with a target drug concentration in plasma Ce= 4-6 mcg/ml depending on the values of the Bispectral Index (BIS), which monitors the depth of anesthesia. Facilitation of endotracheal intubation and the performance of the surgical procedure will be done with the aid of the muscle relaxant rocuronium (0.6 mg/kg of ideal body weight). The maintenance of anesthesia will be carried out exclusively through continuous intravenous infusion of propofol (the TCI model described above) with monitoring of the depth of anesthesia using BIS (value 35-60). Additional postoperative analgesia will be provided with paracetamol and NSAIDs (e.g., ibuprofen). For measuring ONDS, the Sonosite M-Turbo ultrasound machine with a linear probe (13-6 MHz) will be used for all patients. The measurement will be conducted exclusively by one trained examiner.

The ONSD will be measured in both eyes while lying down, using a closed-eye technique in two planes (horizontal and sagittal). Then the mean value will be determined to assess the true ONSD. The measurement will be taken 3 mm posterior to the eyeball, where the distances of reduced echogenicity between the hyperechoic demarcations of the sheath will then be measured. The optic nerve is thought to be the most stretchable and sensitive to intracranial pressure changes at this level. The upper limit of normal ONSD includes 4 mm in infants and 5 mm in children and adults. Although various limits have been proposed, an ONSD greater than 5.8 mm is generally considered abnormal, and elevated ICP should be taken into account.

Non-invasive ICP using ONSD (nICP-ONDS) will be calculated using the formula:
nIKT-ONSD = 5.00 × ONSD – 13.92 mmHg
and it will be expressed in mmHg.

The measurement will be conducted at four different intervals:
1. While the patient is awake before the induction of general anesthesia
2. Immediately after the induction of general anesthesia and before the start of the surgical procedure
3. At the end of the surgical procedure
4. After waking from general anesthesia, before discharge to the recovery room

All data were collected by the end of the procedure in the recovery room, and before discharge to the surgical ward. Patient data were collected from the electronic database, surgical list and anesthesia charts. No additional follow-up during or after hospitalisation was obtained. The obtained data, including ultrasound measurements and hemodynamic profile, was transferred to the investigators' database, where each patient was entered using a specific code/enrollment number to ensure patients' anonymity (only the principal investigator knew patients' identities).

Intervention Type
Procedure/Surgery

Primary outcome(s)
Intracranial pressure measured using data collected from an electronic database of ultrasound images at four time periods during the surgery, which are before the induction of general anesthesia, immediately after the induction of general anesthesia/before the start of the surgical procedure, at the end of the surgical procedure and after waking from general anesthesia, before discharge to the recovery room

Key secondary outcome(s))
1. Optic nerve sheath diameter (ONSD) measured using data collected from an electronic database of ultrasound images at four time periods during the surgery, which are before the induction of general anesthesia, immediately after the induction of general anesthesia/before the start of the surgical procedure, at the end of the surgical procedure and after waking from general anesthesia, before discharge to the recovery room
2. Demographic data (age, gender, body mass index) were measured using data obtained from patients' preoperative anesthesia assessment (electronic database), at one timepoint
3. Comorbidities measured using the ASA physical status classification system from data obtained from patients' preoperative anesthesia assessment (electronic database), at one timepoint
4. The duration of the surgical procedure (minutes) was measured using patient medical records (anesthesia charts) at the end of the surgery (obtained in the recovery room).
5. The amount of saline solution used for irrigation during the procedure (ml) was measured using patient medical records(surgical list) at the end of the surgery (obtained in the operative theatre, before patients' discharge to the recovery room)
6. Hemodynamic parameters: systolic arterial pressure (SAP), diastolic arterial pressure (DAP), mean arterial pressure (MAP) and heart rate (HR), were measured using patient medical records (anesthesia charts) at the time of measuring ONSD

Completion date
31/08/2025

Eligibility

Key inclusion criteria
1. Aged 18 years and over
2 All genders
3. Scheduled for elective functional endoscopic sinus surgery (FESS)
4. Have given their consent to participate

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
90 years

Sex
All

Key exclusion criteria
1. Individuals younger than 18 and older than 90 years
2. Patients with orbital diseases, such as glaucoma, cataracts
3. Conditions resulting from acute or chronic eye trauma
4. Those who have not given their consent to participate

Date of first enrolment
01/09/2024

Date of final enrolment
31/08/2025

Locations

Countries of recruitment
Croatia

Study participating centre
Clinical Hospital Centre Rijeka
Krešimirova 42
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Sponsor information

Organisation
Klinički Bolnički Centar Rijeka

ROR

https://ror.org/027wyhf03

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Clinical Hospital Centre Rijeka

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Katarina Tomulić Brusich, katarinatb@medri.uniri.hr, ktomulic@gmail.com.

All the patients enrolled in the research signed the Informed consent form.
The obtained data, including ultrasound measurements and hemodynamic profile, was transferred to investigators' database, where each patient was entered using a specific code /enrollment number to ensure patients' anonymity (only the principal investigator knew patients' identities).
In the Informed consent form, there is a statement regarding the ethical aspect of the research: "This research will be conducted in accordance with all applicable guidelines, aimed at ensuring the proper conduct of the research and the safety of individuals participating in this scientific study, while respecting the Principles of Good Clinical Practice. The research will ensure adherence to fundamental ethical and bioethical principles – personal integrity (autonomy), justice, beneficence, and non-maleficence – in accordance with the Nuremberg Code and the latest revision of the Helsinki Declaration."
The collected data will be shared/accessible upon publication in a scientific peer-reviewed article.

IPD sharing plan summary
Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			16/07/2025	No	Yes