Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effectiveness and Side Effects of Hydrogen Peroxide Use in Establishing Local Hemostasis in Neurosurgical Procedures: A Clinical Study

Protocol summary

Study aim
To evaluate the effectiveness and safety of 3% hydrogen peroxide irrigation for achieving local hemostasis during neurosurgical procedures, compared with hemostatic methods without hydrogen peroxide.

Design
A two-arm, parallel-group randomized clinical trial involving 96 patients, with 48 participants in each group. Participants will be allocated using computer-generated randomization codes.

Settings and conduct
The study will be conducted among patients undergoing neurosurgical procedures at Imam Reza Hospital, Tabriz University of Medical Sciences, Iran. Eligible patients will be enrolled after informed consent and randomly assigned to either group. Intraoperative data and postoperative outcomes will be collected through medical records and patient follow-up.

Participants/Inclusion and exclusion criteria
Patients aged 18 to 70 years requiring neurosurgery and providing informed consent; exclusion criteria: known hydrogen peroxide allergy, pre-existing cardiovascular disease, and history of venous thromboembolism.

Intervention groups
Intervention group: irrigation of the surgical site with 500 mL of 3% hydrogen peroxide alongside other hemostatic methods; control group: other hemostatic methods without hydrogen peroxide.

Main outcome variables
Intraoperative blood loss; postoperative rebleeding; surgical site infection; venous gas embolism; postoperative pneumocephalus; intraoperative trigeminocardiac reflex.

General information

Reason for update
Acronym
IRCT registration information

IRCT registration number: **IRCT20240811062722N1**
Registration date: **2026-11-04, 1405/08/13**
Registration timing: **prospective**

Last update: **2026-11-04, 1405/08/13**
Update count: **0**

Registration date
2026-11-04, 1405/08/13

Registrant information

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Poia Moaiedy
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Iran (Islamic Republic of)
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Recruitment status
recruiting
Funding source

Expected recruitment start date
2026-11-11, 1405/08/20
Expected recruitment end date
2027-04-20, 1406/01/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effectiveness and Side Effects of Hydrogen Peroxide Use in Establishing Local Hemostasis in Neurosurgical Procedures: A Clinical Study

Public title

Effectiveness and Side Effects of Hydrogen Peroxide for Local Hemostasis in Neurosurgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Definitive diagnosis requiring neurosurgical surgery Age 18-70 years; informed consent from the patient or first-degree relative/legal guardian

Exclusion criteria:
Known allergy to hydrogen peroxide; known pre-existing cardiac disease History of venous thromboembolism

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description
Computer-generated random allocation sequence; allocation concealed; balanced for sex, age and diagnosis.

Blinding (investigator's opinion)
Single blinded

Blinding description
Outcome assessors are blinded to group allocation.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Tabriz University of MedicalSciences

Street address
Golgasht st.

City
Tabriz

Province
East Azarbaijan

Postal code
5166614766

Approval date
2024-10-14, 1403/07/23

Ethics committee reference number
IR.TBZMED.REC.1403.578

Health conditions studied

1

Description of health condition studied
Local hemostasis during neurosurgical procedures

ICD-10 code
G97.31

ICD-10 code description
Intraoperative hemorrhage and hematoma of a nervous system organ or structure complicating a nervous system procedure

Primary outcomes

1

Description
Total intraoperative blood loss (mL), estimated from suction canister volume at the end of surgery

Timepoint
End of surgery (immediately postoperatively)

Method of measurement
Suction canister volume minus irrigation volume, recorded on the intraoperative anesthesia record

Secondary outcomes

1

Description
Surgical site infection (SSI) rate

Timepoint
Postoperative follow-up period

Method of measurement
Regular clinical wound examination (swelling, erythema, tenderness, purulent discharge) and systemic signs of infection, recorded on a checklist

2

Description
Postoperative rebleeding rate

Timepoint
Postoperative follow-up period

Method of measurement
Periodic follow-up visits and review of medical records for re-bleeding events, recorded on checklist

3

Description
Adverse events: venous air embolism, postoperative pneumocephalus, and trigeminocardiac reflex

Timepoint
Intraoperative and postoperative follow-up period

Method of measurement
Anesthesia records during surgery (VAE, TCR) and postoperative imaging (pneumocephalus), recorded on

follow-up checklist

Intervention groups

1

Description
Intervention group: local irrigation of the surgical field with 500 mL of 3% hydrogen peroxide, plus standard hemostatic measures
Category
Treatment - Drugs

2

Description
Control group: standard hemostatic measures without hydrogen peroxide
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza Hospital
Full name of responsible person
pouya Moayedi
Street address
Emam Reza Hospital, Golgasht st., Tabriz, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
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research-vice@tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Pouya Moayedi
Position
Resident
Latest degree
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Other areas of specialty/work
Neurosurgery
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The individual participant data (IPD) will include de-identified baseline patient characteristics, neurosurgical diagnoses and procedure-related information, treatment allocation, intraoperative blood-loss variables, and the prespecified efficacy and safety outcomes, including total blood loss, postoperative rebleeding, surgical site infection, venous gas embolism, postoperative pneumocephalus, and trigeminocardiac reflex. De-identified data from all 96 randomized participants will be made available, subject to applicable ethical and confidentiality requirements. The following supporting documents will also be shared: the final study protocol and its amendments, the statistical analysis plan (SAP), a blank and unsigned version of the informed consent form, the final clinical study report containing aggregated results, statistical analysis codes developed using R and SPSS (if generated), and the study data dictionary. All direct and indirect personal identifiers will be removed or appropriately modified before data sharing. No identifiable medical records or signed participant consent forms will be disclosed.
When the data will become available and for how long
The final study protocol and amendments, statistical analysis plan, blank informed consent form, data dictionary, statistical analysis codes, and final clinical study report will be made available upon publication of the primary study results. De-identified individual participant data and accompanying metadata will become available six months after publication of the primary study results and will remain accessible for at least five years thereafter. Data access will be subject to the necessary ethical and institutional approvals and execution of a data use agreement, where applicable.
To whom data/document is available
Qualified researchers affiliated with universities, research centers, medical institutions, or other recognized research organizations may request access to the study data and supporting documents, regardless of their country of residence. Requests from independent researchers or individuals affiliated with non-academic institutions may also be considered, provided that they demonstrate appropriate scientific qualifications and comply with ethical and confidentiality requirements. All requests will be reviewed by the principal investigator and the research team before approval.
Under which criteria data/document could be used
The shared data and documents may be used exclusively for scientifically valid research purposes, including secondary analyses, validation of study findings, replication of results, comparative research, additional investigations, and systematic reviews and meta-analyses. Applicants must provide their research objectives, research questions or hypotheses, proposed methodology, and statistical analysis plan. Approval from the relevant ethics committee and execution of a data use agreement may be required, as applicable. Any attempt to re-identify participants, link the dataset to identifiable personal information, transfer the data to unauthorized third parties, or use the data for purposes beyond the approved research objectives is strictly prohibited. All recipients must maintain data confidentiality and security and appropriately acknowledge and cite the original study in any resulting

publications.

From where data/document is obtainable

Formal data access requests should be submitted by email to Dr. Farhad Mirzaei, First Academic Supervisor and Scientific Lead of the Study, Department of Neurosurgery, Faculty of Medicine, Tabriz University of Medical Sciences, Imam Reza Hospital, Tabriz, Iran. Email: golzar.farhad@yahoo.com Each request should include the applicant's details, institutional affiliation, research objectives, and relevant supporting scientific documents. All requests will be reviewed by the research team, and the decision will be communicated to the applicant.

What processes are involved for a request to access data/document

Upon receipt of a request, the research team will assess the applicant's scientific qualifications, institutional affiliation, research objectives, and the compatibility of the proposed project with ethical requirements and data use conditions. Applicants must provide a brief description of their research question, proposed analytical methods, requested variables, and, where applicable, approval from their institutional ethics committee. Following approval, a data use agreement must be completed and signed. An initial response will be provided within 30 working days after receipt of a complete application. Upon approval and completion of all applicable ethical and administrative requirements, the requested data and documents will be provided through a secure data transfer method within an additional 30 working days. Incomplete requests or requests that do not comply with ethical and confidentiality requirements may be declined.

Comments

Data and document sharing will be conducted to promote research transparency, reproducibility of findings, and further scientific investigations. All datasets will undergo appropriate de-identification and disclosure risk assessment before being shared. Access will be provided exclusively through a controlled access mechanism in compliance with ethics committee approvals and the regulations of Tabriz University of Medical Sciences. Recipients will be responsible for maintaining confidentiality and ensuring appropriate use of the shared data.