Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Standard Instruments Versus Microdebrider in Endoscopic Sinus Surgery-An Outcome Based Comparative Study: A Tertiary Care Hospital Experience

Protocol summary

Study aim
To compare the outcome after using standard instruments versus microdebrider in endoscopic sinus surgery in the patients of chronic rhinosinusitis with polyposis

Design
A concealed randomized single blinded parallels clinical trial (interventional study)for 130 subjects from 2024 to 2025 which will be followed for 6 months to assess outcome.

Settings and conduct
Trial will be conducted in outpatient and operation theatre departments of Otorhinolaryngology of Bahawalpur Victoria Hospital Bahawalpur Pakistan with randomization of participants by lottery method keeping the participants blinded for groups.

Participants/Inclusion and exclusion criteria
All patients from 15 to ,65 years of age of both the gender having chronic Rhinosinusitis with nasal polyposis requiring endoscopic sinus surgery will be included in the study. Those patients having recurrent disease, history of previous surgery and with nasal septal deviations will be excluded from the study

Intervention groups
Group A patientis will receive one modality of intervention(microdebrider) while group B patients will receive other modality of intervention (standard instruments) during endoscopic sinus surgery

Main outcome variables
Intraoperative bleeding, disease recurrence and synechiae formation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240825062865N1**
Registration date: **2024-09-22, 1403/07/01**
Registration timing: **prospective**

Last update: **2024-09-22, 1403/07/01**
Update count: **0**

Registration date
2024-09-22, 1403/07/01

Registrant information

Name
Asim Shafique

Name of organization / entity
Quaid e Azam medical college Bahawalpur

Country
Pakistan

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+92 300 9687395

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drasimkemc@qamc.edu.pk

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-12-01, 1403/09/11

Expected recruitment end date
2025-12-01, 1404/09/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Standard Instruments Versus Microdebrider in Endoscopic Sinus Surgery-An Outcome Based

Comparative Study: A Tertiary Care Hospital Experience

Public title
Use of microdebrider in endoscopic sinus surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Chronic Rhinosinusitis with nasal polyposis requiring endoscopic sinus surgery
Exclusion criteria:
Recurrent disease with history of previous surgery Sinonasal tumours Chronic Rhinosinusitis along with Deviated nasal septum necessitating septal surgery Concomitant Heart disease, Diabetes Mellitus and Hepatorenal disease Patients on regular antiplatelet drugs
Age
From **15 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **130**
Randomization (investigator's opinion)
Randomized
Randomization description
Lottery method will be used to divide the patients, and all selected subjects will be asked to choose and pick a slip from all mixed up slips whereas half-slips will be containing letter ‘A’ and other half will contain letter ‘B’ and then the particular case will be placed in that respective group accordingly. All patients in Group A will undergo ESS (Endoscopic polypectomy, endoscopic stripping of diseased sinuses mucosa with removal of disease and sinus lavage, Endoscopic middle meatus antrostomies) using microdebrider while in group B patients undergo ESS with conventional routine instruments. The description of specific use of instruments with respect to group A and B will be concealed from the participants.
Blinding (investigator's opinion)
Single blinded
Blinding description
Patients will be asked to pick a slip from a box containing equal mixed slips of letter A and B. Participants will be blinded regarding type of intervention for both A and B groups adopted.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical review committee, Department of medical education QAMC
Street address
Circular road
City
Bahawalpur
Postal code
63100
Approval date
2023-08-21, 1402/05/30
Ethics committee reference number
2245

Health conditions studied

1

Description of health condition studied
Endoscopic sinus surgery for Chronic Rhinosinusitis with polyposis
ICD-10 code
J32.9
ICD-10 code description
Rhinosinusitis, Endoscopic sinus surgery. Microdebrider

Primary outcomes

1

Description
Intraoperative blood loss
Timepoint
2 hours
Method of measurement
Measurement of suction bottles and weight of soaked guaze pieces

Secondary outcomes

1

Description
Nasal synchiae
Timepoint
2 months
Method of measurement
Nasoendoscopy

2

Description
Disease recurrence
Timepoint
6 months
Method of measurement

Nasoendoscopy and computed tomography

Intervention groups

1

Description
The participants who will undergo surgical treatment with microdebrider will be labelled as intervention group while those who will undergo surgical treatment with standard conventional instruments will be labelled as comparison group.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Out patient Department of Bahawalpur Victoria Hospital Bahawalpur Punjab
Full name of responsible person
Areej sajid
Street address
ENT Department BVH. Circular road
City
Bahawalpur
Postal code
63100
Phone
+92 337 7506123
Email
Dr.merryshah@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bahawalpur Victoria Hospital Bahawalpur
Full name of responsible person
Muhammad Asim Shafique
Street address
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63100
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drasimkemc@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bahawalpur Victoria Hospital Bahawalpur
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
Quaid e Azam medical college
Full name of responsible person
Muhammad Asim Shafique
Position
Consultant
Latest degree
Medical doctor
Other areas of specialty/work
Ear, Nose, and Throat
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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Full name of responsible person
Ansar Javed
Position
Post graduate resident
Latest degree
Medical doctor
Other areas of specialty/work
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+92 342 7229607

Email

ansarbhatti57@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Quaid e Azam medical college

Full name of responsible person

Areej sajid

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Ear, Nose, and Throat

Street address

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City

Bahawalpur

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Punjab

Postal code

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Phone

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Email

Dr.merryshah@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data will be collected on a predestined proforma/ question are for every patient that can be made available for sharing.

When the data will become available and for how long

When all the data of all participants is completed and analysed. It will take the time duration when the complete follow up period is over.

To whom data/document is available

For all the investigators and colleagues working in the institution and may be shared to other institutional colleagues on request after the approval.

Under which criteria data/document could be used

Requests of data sharing and availability will be analysed and considered by the team of authors/investigators and in case the matter is agreed.l, will be forwarded to the department of institutional review board/ ethical committee for final approval.

From where data/document is obtainable

The registrar of the relevant department of institution through postal address. Bahawalpur Victoria Hospital circular road, Bahawalpur Pakistan, dr.shahzadbwp@gmail.com

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

After the arrival of requests, these will be put up for consideration before the team of investigators and if accepted, will be forwarded to ethical board of institutions for final approval

Comments