Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of zinc impregnated pack (compared to traditional methods) on reducing the incidence of sore throat in patients undergoing Septorhinoplasty

Protocol summary

Study aim
effect of zinc impregnated pack in septorhinoplasty
Design
Clinical trial without control group, parallel groups, one-way blinded, phase 3 randomization on 220 patients, data will enter into SPSS software version 21 to compare the incidence of sore throat between four studied groups by Chi squre test and to compare the severity of sore throat , Kruskal wallise test will be used and Bonferroni test will be used to compare the two pairs.
Settings and conduct
220 patients with ASA class I or II candidate for septorhinoplasty in Amir-Al Momenin Hospital ,Rasht will assign to the study. They will be randomly divided into 4 groups: 1th gas+N/S , 2nd gas + zinc, 3rd wet vibril with N /S 4th vibril+ zinc solution. principle researcher and patients will be blinded to the study groups.
Participants/Inclusion and exclusion criteria
220 patients (A.S.A class 1 OR 2) receiving GA and endotracheal intubation for septorhinoplasty
Intervention groups
Patients are divided into four groups. In the first group, after induction of anesthesia and endotracheal intubation, a throat pack of high quality gas with N / S will be placed. In the second group, the throat pack will be prepared with gas impregnated with zinc solution, in the third group, wet vibril with N / S and in the fourth group, vibril impregnated with zinc solution will be placed.
Main outcome variables
post operative sore throat (POST)

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200527047578N1**
Registration date: **2020-09-28, 1399/07/07**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-28, 1399/07/07**
Update count: **0**
Registration date
2020-09-28, 1399/07/07

Registrant information
Name
Fatemeh Taghi pour
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 13 4263 3310
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srudsari@yahoo.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-08-22, 1399/06/01
Expected recruitment end date
2021-08-23, 1400/06/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of zinc impregnated pack (compared to traditional methods) on reducing the incidence of sore throat in patients undergoing

Septorhinoplasty

Public title
Effect of zinc in reduce of post operative sore througth
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
candidates for septorhinoplasty class 1 or 2 ASA receiving GA and septorhinoplasty
Exclusion criteria:
patient with History of sore throat upper respiratory tract disease active common cold positive history of receiving analgesic before surgery drug addiction positive history of difficult intubation allergic reaction to zinc
Age
From **18 years** old to **55 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **220**
Randomization (investigator's opinion)
Randomized
Randomization description
The sampling method of this study is based on gradual referrals of patients and rhinoplasty surgery is based on random blocks whose sequences are randomly assigned through Random allocation software. The relevant list is kept in the ENT Research Center and after starting the study, based on a random list assigned to four groups (1) pharyngeal pack of wet Vibrille with normal saline (2) pharyngeal pack of gas Wet with normal saline (3) zinc-impregnated Vibrilie pack (4) normal saline-damped vibrille
Blinding (investigator's opinion)
Single blinded
Blinding description
After obtaining the agreement of the ethics committee of Guilan University of Medical Sciences, a written agreement will be given to all patients participating in this study, in which the risks, benefits and steps of the work will be explained. The study will be designed randomly. So that patients will be unaware of their group. 220 patients who are candidates for septorhinoplasty surgery who are class I or II (ASA) and are candidates for general anesthesia and GA and receiving endotracheal intubation will be randomly assigned to a single blind blind study.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Guilan University of Medical Sciences
Street address
Valiasr Boulevard, at the end of Fathi Alley, No. 3
City
roudsar
Province
Guilan
Postal code
4481873111
Approval date
2019-12-21, 1398/09/30
Ethics committee reference number
IR.GUMS.REC.1398.429

Health conditions studied

1

Description of health condition studied
1- The effect of zinc impregnated pharyngeal pack in comparison with other conventional methods on sore throat after septorhinoplasty 2_ The effect of zinc impregnated pharyngeal pack on postoperative vomiting
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Postoperative sore throat with standard rating system and postoperative vomiting nausea (Verbal rating scale
Timepoint
Postoperative sore throat and postoperative vomiting nausea will be assessed at 0,2,4,6,24 hours.
Method of measurement
Sore throat will be assessed with a standard rating system. (Zero hour) Post intensity is divided into four categories 0-3.0: Absence of sore throat, 1: Existence of mild discomfort that is expressed only by asking questions.2: The presence of moderate sore throat, which manifests itself.3: Existence of very severe sore throat that causes voice change and voice violence

Secondary outcomes

empty

Intervention groups

1

Description
All patients participating in this study will be given a

written agreement outlining the risks, benefits, and steps involved. Patients are randomly divided into four intervention groups (without control group): (1) Patients with a pharyngeal pack made of wet vibrile with normal saline. BPI wibril made in Iran - Iran Medical Bands Manufacturing Company - will be used for the pharyngeal pack. The vibrils are the same size as the cut gas. To prepare the pack, the vibrils will be rolled in containers containing 0.9% normal saline to be evenly impregnated with the above solution.

Category

Prevention

2

Description

Intervention group: In the second group, the bottom pack of the throat made of gas impregnated with zinc solution will be placed. 10 C 10 cm Cm made of English yarn 1/20- Number of yarn strands per square centimeter According to standard 3061- Density of yarn per 10 cm According to standard 3061- Density of powder at 10 cm According to standard 3061- Width of gas yarn at least 5 mm /0. Zinc sulfate heptahydrate solution of Behsan Sar company is white and soluble in water, it will be used to impregnate the gas.To prepare the gas pack, it will be rolled in containers containing zinc sulfate heptahydrate solution to be uniformly impregnated with the above solutions.

Category

Prevention

3

Description

Intervention group: In the third group, wet Vibrile intervention with N / S will be used. Intervention group. The properties of Vibrile and Normal Saline are in accordance with the explanations given in the previous interventions

Category

Prevention

4

Description

Intervention group:: In the fourth intervention group, Vibrile impregnated with zinc solution will be placed. The specifications of Vibrile and Zinc used and how to use it are in accordance with the previous cases

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiral Momenin Hospital

Full name of responsible person

Fatemeh Taghi Pour Salehi

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Mohammad Reza Naghi Pour

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Guilan Medical University

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

Rasht University of Medical Sciences

Full name of responsible person

Fateme Taghi Pour Salehi

Position

Resident

Latest degree

Medical doctor
Other areas of specialty/work
Anesthesiology
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Person responsible for scientific inquiries

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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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
deidentified individual participant data (IPD) collected in this study study protocol statistical analysis plan clinical study reports
When the data will become available and for how long
beginning from 2021-2022
To whom data/document is available
academic researchers
Under which criteria data/document could be used
only academic researchers
From where data/document is obtainable
corresponding author/Dr Haddadi so_haddadi@yahoo.com
What processes are involved for a request to access data/document
They send their request with academic e-mail./among one month
Comments