

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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 square test and to compare the severity of sore throat, Kruskal Wallis 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: 1st 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

Email address

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

Public title

Effect of zinc in reduce of post operative sore through

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 Vibrillie 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

Valiasr Boulevard, at the end of Fathi Alley, No. 3

City

Roudsar

Province

Guilan

Postal code

4481873111

Phone

+98 13 4263 3310

Email

srudsari@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Mohammad Reza Naghi Pour

Street address

Valiasr Boulevard, at the end of Fathi Alley, No. 3

City

Roudsar

Province

Guilan

Postal code

4481873111

Phone

+98 31 4263 3310

Email

sroudsari@yahoo.com

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
Street address
Valiasr Boulevard, at the end of Fathi Alley, No. 3
City
Roudsar
Province
Guilan
Postal code
4481873111
Phone
+98 13 4263 3310
Email
sroudsari@yahoo.com

Person responsible for scientific 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
Street address
Valiasr Boulevard, at the end of Fathi Alley, No. 3
City
Roudsar
Province
Guilan
Postal code
4481873111
Phone
+98 13 4263 3310
Email
sroudsari@yahoo.com

Person responsible for updating data

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
Street address
Valiasr Boulevard, at the end of Fathi Alley, No. 3
City
Roudsar
Province
Guilan
Postal code
4481873111
Phone
+98 13 4263 3310
Email
sroudsari@yahoo.com

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