

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of low-pressure suction drainage on prevention of pharyngocutaneous fistula after total laryngectomy.

Protocol summary

Summary

Pharyngocutaneous fistula (PCF) is a serious complication after total laryngectomy. It causes morbidity and prolonged admission in hospital. We want to find out the efficacy of this method to prevent fistula. Forty patients who will be candidate for total laryngectomy attending to Rasool akram and Firuzgar hospital, will be included in this study. We will allocate them in two intervention and control groups through block balanced randomization. In intervention group, after total laryngectomy, neopharynx will be repaired in a T shape. After that, we put a drain on the neopharynx, which takes out from submentum area. We will connect the drain to continuous low negative pressure vacuum (80-120 mmhg) in the third day after surgery until 10 days. If the PCF occurs we will continue suction drainage until discharge less than 25 cc during 24 hours in which suction drainage will be brought out. We do not put drain in 20 patients in the control group. The surgeon will be blind to the allocation. Inclusion criteria: Total laryngectomy. Main outcome: pharyngocutaneous fistula rate. Second outcome: time of recovery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017022532765N1**

Registration date: **2017-04-09, 1396/01/20**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-04-09, 1396/01/20

Registrant information

Name

Zhaleh Faham

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2017-06-24, 1396/04/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of low-pressure suction drainage on prevention of pharyngocutaneous fistula after total laryngectomy.

Public title

The effect of low-pressure suction drainage on pharyngocutaneous fistula.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Total laryngectomy Exclusion criteria:-

Age

No age limit

Gender

Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: 40

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran University of Medical Sciences

Street address
Hemat highway. Tehran

City
Tehran

Postal code

Approval date
2015-09-23, 1394/07/01

Ethics committee reference number
105/1102/ب/IR.IUMS.REC.94

Health conditions studied

1

Description of health condition studied
pharyngocutaneous fistula

ICD-10 code
z92

ICD-10 code description
Personal history of medical treatment

Primary outcomes

1

Description
Pharyngocutaneous fistula

Timepoint
daily from the third day after surgery

Method of measurement

Physical examination

Secondary outcomes

1

Description
time of recovery

Timepoint
after occurrence

Method of measurement
amount of fistula discharge with examination

Intervention groups

1

Description
Intervention group: In intervention group, after total laryngectomy, neopharynx will be repaired in a T shape. After that, we put a drain on the neopharynx, which takes out from submentum area. We will connect the drain to continuous low negative pressure vacuum (80-120 mmhg) in the third day after surgery until 10 days. If the PCF occurs we will continue suction drainage until discharge less than 25 cc during 24 hours in which suction drainage will be brought out.

Category
Prevention

2

Description
control: without drain

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Rasool akram hospital

Full name of responsible person
Zhaleh Faham

Street address
Niayesh street, Sattarkhan street

City
Tehran

2

Recruitment center

Name of recruitment center
Firuzgar hospital

Full name of responsible person
Zhaleh Faham

Street address
Valadi street, Behafarin street, Valiasr square

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Iran University of Medical Sciences

Full name of responsible person

Saied javad Musavi

Street address

Iran university of medical science, beside Milad Tower, Hemat Highway

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for research of Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Otorhinolaryngology, Head and Neck surgery group; of Iran University of Medical Sciences

Full name of responsible person

Zhaleh Faham

Position

ENT resident

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty