

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of intravenous vitamin C on the incidence of pharyngocutaneous fistula after total laryngectomy in patients with laryngeal cancer

Protocol summary

Study aim

Determining and comparing the effect of vitamin C on the incidence of pharyngocutaneous fistula after total laryngectomy in patients with laryngeal cancer

Design

A controlled, parallel-group, single-blind, randomized, phase 3 clinical trial on 32 patients. Blocks of 4 were used for randomization.

Settings and conduct

Patients with laryngeal SCC referred to the Amir Alam Hospital in Tehran, who underwent total laryngectomy and bilateral neck dissection surgery with the same technique in 2022-2024, will be included. Patients are randomly divided into two groups of control and intervention using quadruple blocking. In the intervention group, vitamin C ampoules of Alborz Drug Company in the amount of 1G are injected intravenously 2 times a day with a volume of 10CC in each turn for 7 days. In the control group, distilled water with the same volume and the same method will be used. The study was designed to be single-blind. To follow up the patients, one month after the surgery, by referring to the head and neck clinic for an examination, the rate of fistula formation in both groups will be measured and will be recorded.

Participants/Inclusion and exclusion criteria

Patients with SCC type of laryngeal cancer referred to the Amir Alam Hospital Department in Tehran, who underwent total laryngectomy and bilateral neck dissection surgery with the same technique in 2022-2024, will be included in this study. Exclusion criteria are history of diabetes, preoperative radiotherapy, anemia, and hypoalbuminemia before surgery.

Intervention groups

In the intervention group, vitamin C ampoules of Alborz Drug Company in the amount of 1G are injected intravenously every 12 hours with a volume of 10CC

each time for 7 days. In the control group, distilled water with the same volume and the same method will be used.

Main outcome variables

The rate of pharyngocutaneous fistula formation after surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220605055077N1**

Registration date: **2022-07-11, 1401/04/20**

Registration timing: **prospective**

Last update: **2022-07-11, 1401/04/20**

Update count: **0**

Registration date

2022-07-11, 1401/04/20

Registrant information

Name

Zahra Sanaye pasand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3356 1678

Email address

z.sanaye.p@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2024-07-22, 1403/05/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of intravenous vitamin C on the incidence of pharyngocutaneous fistula after total laryngectomy in patients with laryngeal cancer

Public title
The effect of intravenous vitamin C on the incidence of pharyngocutaneous fistula after total laryngectomy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with SCC laryngeal cancer have undergone total laryngectomy and bilateral neck dissection with the same technique.
Exclusion criteria:
Diabetes mellitus Preoperative radiotherapy Anemia before surgery Preoperative hypoalbuminemia

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: 32

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is block. Four blocks are defined from intervention group (A) and control (B). (AABB, ABAB, ABBA, BABA, BAAB) It is written on cards 1 to 6 and the cards are placed in the envelope. The cards are then randomly selected and a random string is made from the sequence of selected cards. Patients in the intervention and control groups are included in the study based on this sequence.

Blinding (investigator's opinion)
Single blinded

Blinding description
The study was designed to be one-sided blindness and the study participants did not know whether they were in the intervention or control. But surgeon and researcher are informed of it. It is mentioned in the consent letter that the patient will be randomly placed in one of the intervention or control groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Amir A'lam Hospital Complex

Street address

Amir A'lam hospital, North Sa'di Ave , Darvaze Dolat

City

tehran

Province

Tehran

Postal code

114576511

Approval date

2022-06-23, 1401/04/02

Ethics committee reference number

IR.TUMS.AMIRALAM.REC.1401.017

Health conditions studied

1

Description of health condition studied

laryngeal cancer

ICD-10 code

C32

ICD-10 code description

Malignant neoplasm of larynx

Primary outcomes

1

Description

The incidence of pharyngocutaneous fistula after total laryngectomy

Timepoint

One month after laryngectomy

Method of measurement

Using examination and observation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Vitamin C ampoule of Alborz Daroo company in the amount of 1G by injection intravenous BD or 2 times a day with a volume of 10CC in each turn for 7 days

Category

Treatment - Drugs

2

Description

Control group: Distilled water for injection BD or 2 times a day with a volume of 10CC each time for 7 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Otolaryngology and Head and Neck Surgery Center of Amir Alam Hospital Departement, Tehran

Full name of responsible person

Zahra Sanaye Pasand

Street address

Enghelab St., North Saadi, ENT Clinic of Amir Alam Hospital

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141765371

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z.sanaye.p@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotohi

Street address

Keshavarz Boulevard, Qods Street

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1417653761

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Zahra Sanaye Pasand

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Ear, Nose, and Throat

Street address

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Full name of responsible person

Zahra Sanaye Pasand

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available