

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Oct 2026

Comparative study of the relative frequency of short-term complications of percutaneous dilatation tracheostomy Vs open tracheostomy in Alzahra hospital

Protocol summary

kolahdouzan@med.mui.ac.ir

Summary

The aim of this study is to determine Comparative study of the relative frequency of short-term complications of percutaneous dilatation tracheostomy Vs open tracheostomy in Alzahra hospital. patients who needed the non-emergency tracheostomy are included and with Emergency patients, dissatisfaction with the tracheostomy and coagulopathy are excluded. 40 patients who intubated in ICU division and need long term ventilation support, are selected and divided in two groups randomly, group1: Percutaneous dilatation tracheostomy. Group2: surgical tracheostomy . primary outcome is to assay short-term complications.

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2013-03-21, 1392/01/01

Expected recruitment end date

2015-03-21, 1394/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016122529726N2**

Registration date: **2017-02-13, 1395/11/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-02-13, 1395/11/25

Registrant information

Name

Mohsen Kolahdouzan

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3669 2277

Email address

Scientific title

Comparative study of the relative frequency of short-term complications of percutaneous dilatation tracheostomy Vs open tracheostomy in Alzahra hospital

Public title

Evaluation of short-term complications tracheostomy

Purpose

Supportive

Inclusion/Exclusion criteria

inclusion: patients who needed the non-emergency tracheostomy Exclusion: Emergency patients; dissatisfaction with the tracheostomy; coagulopathy

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample sizeTarget sample size: **40****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Isfahan University of Medical Sciences

Street address

Isfahan

City

Isfahan

Postal code**Approval date**

2008-09-22, 1387/07/01

Ethics committee reference number

388037

Health conditions studied**1****Description of health condition studied**

Tracheostomy Complication

ICD-10 code

J95.0

ICD-10 code description

Tracheostomy malfunction

Primary outcomes**1****Description**

short term complication

Timepoint

before surgery and two weeks after surgery

Method of measurement

checklist

Secondary outcomes**1****Description**

surgery duration time

Timepoint

intraoperative

Method of measurement

Minute

Intervention groups**1****Description**

percutaneous dilatation tracheostomy as a case group

Category

Treatment - Surgery

2**Description**

control: surgical tracheostomy

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Isfahan University of Medical Sciences

Full name of responsible person

Mohsen Kolehdozan

Street address

Surgery Department, Alzahra Hospital, Soffeh Avenue, Isfahan

City

Isfahan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Isfahan University of Medical Sciences

Full name of responsible person

Dr.Mehdi Nematbakhsh

Street address

Isfahan University of medical Sciences

City

Isfahan

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

Yes

Title of funding source

Isfahan 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
Isfahan University of Medical Sciences
Full name of responsible person
Dr.Mohsen Kolahdouzan
Position
assistant professor
Other areas of specialty/work
Street address
Isfahan University of Medical Sciences
City
Isfahan
Postal code
Phone
+98 31 3620 1293
Fax
Email
kolahdouzan@med.mui.ac.ir
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Isfahan university of medical sciences
Full name of responsible person
Gholamreza Mohajeri
Position
Associate professor
Other areas of specialty/work
Street address
Surgery Department, Alzahra Hospital, Soffeh Avenue, Isfahan
City
Isfahan
Postal code

8174673461

Phone
+98 31 3620 1293
Fax
+98 31 3620 1250
Email
gh_mohajeri@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Mohsen Kolahdouzan
Position
assistant professor
Other areas of specialty/work
Street address
Surgery Department, Alzahra Hospital, Soffeh Avenue, Isfahan
City
Isfahan
Postal code
8174673461
Phone
+98 31 3620 2020
Fax
Email
kolahdouzan@med.mui.ac.ir
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