Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Oct 2026

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

Protocol summary

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.

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

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Name of organization / entity

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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

Scientific title

Comparative study of the relative frequency of short-term complications ofpercoutaneous dilataion 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 size
Target 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
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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 Kolahdouzan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan University of Medical Sciences
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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
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

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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