

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Comparison of three methods in improving Bag Mask Ventilation

Protocol summary

Summary

In a single blind randomized clinical trial, we studied 300 patients with ASA class I, II (American Society of Anesthesiologists), Mallampati class (I, II), and age over 55 years in three groups. We tested the hypothesis that placing a packed (two folded) gauze (8 layer - 10 x 10 cm) in each buccal cavity in edentulous patients results in easier bag mask ventilation compared with edentulous patients who have had their dentures removed or were left in the place. Our Exclusion criteria were full stomach patients, patients with NG tube, Fascial Anomaly, Mallampati Class III, IV, Beard and Snoring. A prospective blind randomized clinical trial performed in Nikookari teaching hospital in Tabriz-Iran. After induction of anesthesia, in group G dentures were removed and in each buccal space an eight-layer 10x10 cm gauze and an oral airway were placed. In group D the dentures and an oral airway were left in place. In group C (control), after removing dentures just an appropriate oral airway was placed. Then, each three group underwent bag-mask ventilation. Success of bag-mask ventilation was considered as increase in ETCO₂ to more than 20 mmHg and back to Base-Line with FGF=3 Lit/min and APL valve pressure at 20 cmH₂O

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138901042496N2**
Registration date: **2010-03-24, 1389/01/04**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-03-24, 1389/01/04

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2008-11-21, 1387/09/01

Expected recruitment end date

2009-11-20, 1388/08/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of three methods in improving Bag Mask Ventilation

Public title

Comparison of three methods in improving Bag Mask Ventilation

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: Edentulous patient's considering ASA classification (class I and II), Mallampati grading system (grade I and II) 2- age (55-100) Exclusion criteria: 1- full stomach 2- NG tube 3- Fascial Anomaly 4- Mallampati Class III, IV 5- Beard 6- Snoring

Age

From **55 years** old to **100 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **300**

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**

Research Vice chancellor of Tabriz University of Medical Sciences

Street address

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Approval date

empty

Ethics committee reference number

8713

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

The Effect of Using Packed Gauze in the Edentulous Patients on facility of Bag Mask Ventilation

ICD-10 code

T88.4

ICD-10 code description

failed or difficult intubation

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

Successful bag mask ventilation rates

Timepoint

3 minute

Method of measurement

increase in End Tidal co2 to 20 mm Hg and back to baseline with 3 L/min fresh gas flow and the adjustable pressure limiting valve at 20 cm H2O.

Secondary outcomes

empty

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

placing a packed (two folded) gauze (8 layer - 10 x 10 cm) in each buccal cavity in edentulous patients

Category

Other

2**Description**

we placed only an oral airway

Category

N/A

3**Description**

The dentures and an oral airway were left in place.

Category

Treatment - Other

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

Nikookari hospital

Full name of responsible person**Street address****City**

Tabriz

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

Research Vice chancellor of Tabriz University of Medical Sciences

Full name of responsible person

Mir Ali Eteraf Oskouei

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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

Research Vice chancellor of Tabriz 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**

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Full name of responsible person

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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