# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## Clinical comparison of two submental intubation methods (Altmeyer and Seldinger) in patients candidates for fixation of maxillofacial injuries

## Protocol summary

**Study aim**
Clinical comparison of two submental intubation methods (Altmeyer and Seldinger) in patients candidates for fixation of maxillofacial injuries

**Design**
This clinical trial study was a parallel-group, single-blind, randomized study on 22 patients. The rand function of Excel software was used for randomization.

**Settings and conduct**
This clinical trial study will be conducted on 22 patients who are candidates for fixation of maxillofacial injuries referred to Shahid Rahmanun Hospital in 2025. The outcome assessors, caregivers, and data analysts will not be aware of the grouping of the samples and the type of surgery performed.

**Participants/Inclusion and exclusion criteria**
Patients who were candidates for fixation of maxillofacial injuries and submental intubation under general anesthesia were included in the study. Patients with traumatic brain injury, coagulopathy, psychiatric diseases, polytrauma and requiring long-term respiratory support will be excluded from the study.

**Intervention groups**
Intervention group 1: an incision is made in the paramedian area under the jaw. Using arterial forceps, a blunt tunnel is created towards the floor of the mouth and after suction, the endotracheal tube (ETT) cuff is evacuated and removed from the tunnel. Then the ETT is separated from the circuit, passed through the tunnel with the help of forceps and connected in the new location. Intervention group 2: In this method, a tracheostomy kit is used. The needle with the sheath is inserted into the submental area and after appearing in the mouth, the guide wire is inserted and the path is widened. After creating the path, a similar process is performed as in the first group, including evacuation and passage of the cuff and ETT through the submental tunnel and finally, the tube is connected to the respiratory circuit.

**Main outcome variables**
Bleeding, duration of intubation, skin scar

## General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20250419065388N1**
Registration date: **2025-05-08, 1404/02/18**
Registration timing: **prospective**

Last update: **2025-05-08, 1404/02/18**
Update count: **0**

**Registration date**
2025-05-08, 1404/02/18

**Registrant information**
**Name**
Reza Mazloumi
**Name of organization / entity**
**Country**
Iran (Islamic Republic of)
**Phone**
+98 35 3626 0001
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fatalprowling@yahoo.com

**Recruitment status**
**Recruitment complete**
**Funding source**

**Expected recruitment start date**
2025-06-22, 1404/04/01
**Expected recruitment end date**
2026-06-22, 1405/04/01
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Clinical comparison of two submental intubation methods (Altmeyer and Seldinger) in patients candidates for fixation of maxillofacial injuries

**Public title**
Comparison of two submental intubation methods (Altmeyer and Seldinger) in fixation of maxillofacial injuries

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Patients who are candidates for fixation of maxillofacial injuries Need for submental intubation

**Exclusion criteria:**
Patients with traumatic brain injury Patients with coagulopathy Patients with psychiatric illnesses Patients with polytrauma requiring multiple surgeries Patients requiring long-term respiratory support

**Age**
From **20 years** old to **60 years** old

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**

- Care provider
- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **22**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Randomization of eligible patients is done in random blocks of 4 using the RAND option of Excel software. Then, for concealment, a code is considered for each of the samples and a coded envelope is allocated and sealed in the envelope. None of the people present in the study are aware of the groupings from the time of allocation to the implementation.

**Blinding (investigator's opinion)**
Single blinded

**Blinding description**
The outcome assessors, the patient's caregivers, including nurses and paramedics, were unaware of the type of intervention performed. The only person performing the procedure (surgeon) was informed of the grouping and type of intervention for each group only at the time of the procedure, due to the need for correct and standardized implementation. When recording data, the groups were recorded as A and B, and the statistical analyst was unaware of which type of intervention each group belonged to.

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics Committee of Dentistry Faculty of Shahid Sadoughi University of Medical Sciences Yazd

**Street address**
Faculty of Dentistry, Marat Blvd, Imam Reza Blvd, Deha Fajr Blvd, Yazd

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**Postal code**
8914881167

**Approval date**
2024-09-22, 1403/07/01

**Ethics committee reference number**
IR.SSU.DENTISTRY.REC.1403.040

## Health conditions studied

### 1

**Description of health condition studied**
submental intubation

**ICD-10 code**
T88.4

**ICD-10 code description**
Failed or difficult intubation

## Primary outcomes

### 1

**Description**
Time required for intubation

**Timepoint**
The time required for intubation is measured from the onset of anesthesia and the initiation of intubation to connection to the mechanical ventilator.

**Method of measurement**
The time interval between the incision or needle passage and the ventilator connection

### 2

**Description**
bleeding

**Timepoint**
Bleeding is recorded from the beginning of the intervention to the end of the surgery.

**Method of measurement**

Bleeding score according to the Ramaraj scale

**3**

**Description**
Skin scar
**Timepoint**
At 1 and 3-month follow-up after intervention
**Method of measurement**
vancover scar test

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
In patients assigned to the Altemir group, submental intubation is performed using the classic Altemir technique. First, the patient's head and neck are extended, and the submental region is thoroughly disinfected. Adhering strictly to sterile technique, a 1.5–2 cm skin incision is made in the paramedian submental area, approximately 1 cm below and parallel to the lower mandibular margin, at the junction of the medial one-third and lateral two-thirds of the distance between the mandibular symphysis and the mandibular angle. The side for submental intubation is chosen based on the location of any mandibular fractures.Next, a medium-sized arterial forceps is used to perform blunt dissection from the skin incision toward the floor of the mouth, following the lingual aspect of the mandible. The tips of the arterial forceps tent the mucosa of the floor of the mouth and then enter the oral cavity. Inside the mouth, the tongue is retracted to the opposite side for improved visualization, thereby creating the submental tunnel. The tunnel is then progressively dilated by opening the forceps.After thorough suctioning of oral secretions, the cuff of the endotracheal tube (ETT) is completely deflated, and the pilot balloon is grasped with the arterial forceps and pulled through the submental tunnel. Once exteriorized, the cuff is reinflated. The forceps are reinserted through the tunnel into the mouth, and the universal connector of the oral ETT is disconnected from the ventilator circuit and removed. The ETT is then grasped with the forceps, withdrawn through the submental tunnel, and positioned in the submental region. Finally, the submental ETT is reconnected—via its universal connector—to the respiratory circuit.
**Category**
Treatment - Surgery

**2**

**Description**
Intervention Group 2 (Seldinger Technique):In patients assigned to the Seldinger group, submental intubation is performed using a percutaneous tracheostomy kit. First, the patient's head and neck are extended, and the submental region is thoroughly disinfected. Under strict sterile conditions, a needle with its introducer sheath is inserted into the paramedian submental area—approximately 1 cm below and parallel to the lower mandibular margin, at the junction of the medial one-third and lateral two-thirds of the distance between the mandibular symphysis and angle. Once the needle tip appears in the oral cavity, the needle is withdrawn, leaving the sheath in place.Next, a guidewire is passed through the sheath. As soon as the guidewire enters the mouth, an assistant secures it firmly. An introducer tube is then advanced over the guidewire to establish the submental tract. The tract is progressively dilated using a dilator, which is rotated over the guidewire. When sufficient dilation is achieved, a medium-sized arterial forceps is passed through the tract until its tips emerge into the oral cavity.After complete suctioning of oral secretions, the cuff of the endotracheal tube (ETT) is fully deflated, and the pilot balloon is grasped with the arterial forceps and pulled through the submental tunnel. The cuff is then reinflated. Next, the arterial forceps is reinserted through the submental tunnel into the mouth; the universal connector of the oral ETT is disconnected from the ventilator circuit and removed. The ETT is then firmly grasped with the forceps and withdrawn through the submental tunnel until its tip lies in the submental region. Finally, the submental ETT is reconnected—via its universal connector—to the respiratory circuit.Demographic data and the time required to complete each intubation procedure—defined as "incision time" in the Altemir technique and as "needle-to-reconnection time" in the Seldinger technique—will be recorded. Apnea duration (time needed to convert from oral to submental intubation), intraoperative complications such as damage to the ETT or its components, difficulty dilating the tract, or tissue entrapment during pilot balloon inflation will also be documented.
**Category**
Treatment - Surgery

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Shahid Rahnemoon hospital
**Full name of responsible person**
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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Yazd University of Medical Sciences

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Dr. Amir Houshang Mehrparvar

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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**
Yazd 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**
Yazd University of Medical Sciences

**Full name of responsible person**
Reza Mazloumi

**Position**
Resident

**Latest degree**
Medical doctor

**Other areas of specialty/work**
Dentistry

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is 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

**Title and more details about the data/document**
All data is potentially shareable after de-identifying individuals.

**When the data will become available and for how long**
Access begins one month after publication of this clinical trial study article.

**To whom data/document is available**
All researchers working in educational and medical institutions around the world can access the data.

**Under which criteria data/document could be used**
After the publication of the article resulting from this project, researchers can request access to the project data by sending an email to the address of the responsible author of the project, and within one month, coded information without personal patient information will be sent to the researchers.

**From where data/document is obtainable**
After the publication of the article resulting from this project, researchers can request access to the project data by sending an email to the address of the responsible author of the project, and within one month, coded information without personal patient information will be sent to the researchers.

**What processes are involved for a request to access data/document**
After the publication of the article resulting from this project, researchers can request access to the project data by sending an email to the address of the responsible author of the project, and within one month, coded information without personal patient information will be sent to the researchers.

**Comments**