Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Clinical Trial of Awake Nasotracheal Fiberoptic Intubation: A Comparison of Three Techniques of Conscious Sedation with Remifentanil ,Ketamin and Propofol Without Muscle Relaxants on hemodynamic Parameters in Tempro-mandibular Joint Ankylosis Surgery

Protocol summary

Summary

(1) Objectives: Maintenance and safety of the airway is one of the anesthesiologist's goals and skills with intubation is achieved. Although in some reasons, such as difficult air way, awake-approach is recommended by various techniques such as "conscious sedation" . Using the device for fiberoptic intubation typically is used in the operating room. For the patient comfort and minimizing damage to the tracheal tube during awake intubation by drugs such as remifentanil, ketamine and propofol can be used sometimes under local anesthesia. Awake nasotracheal fiberoptic intubation without muscle relaxants has been reported in some papers. (2) Design: This paper compares three methods of single dose usage of IV-Rremifentanil -Propofol and Ketamine as for "conscious sedation" for fiberoptic intubation device that are evaluated complications of intubation, hemodynamic stability, and study of patients satisfaction in maxillofacial Surgery. The fiberoptic device used by an anesthesiologist and anesthetist is responsible for intubation. (3) Setting and conduct: Fiberoptic intubation with maintenance of spontaneous breathing is a gold standard in cases of difficult airway. The usual treatment for fiberoptic intubation technique can be done under general anesthesia, But for the conscious patients should be careful to do by regional anesthesia with patients tolerance and cardiovascular Hemodynamic stability - provided for safe intubation. (4) Participants including major eligibility criteria: The patients with Physical status of I and age 15 to 60 years are enrolled; The Patients with systemic disease and or taking any medication will excluded. (5) Intervention: In patient with Conscious status setting started by midazolam 0.05 mg/kg and fentanyl 0.1 microgram/kg as intraveneus premedication , before fiberoptic procedure, and then route of the patient's air way anesthethized with a local anesthia and then patients will be divided into three groups, the first group: remifentanil, group II: ketamine, group III: propofol is administered as an intravenous infusion, followed awake- nasotracheal fiberoptic intubation is performed (6) main outcome measures:In this method working quickly, complications during intubation, patients satisfaction, and satisfaction anesthesiologist , patient's hemodynamic stability for three-drug techniques (remifentanil, ketamine and propofol) are compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201208061674N4**
Registration date: **2012-10-15, 1391/07/24**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-10-15, 1391/07/24

Registrant information

Name
Hamid Reza Eftekharian
Name of organization / entity
Shiraz University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 71 3636 4001
Email address
eftekharhr@sums.ac.ir

Recruitment status

Recruitment complete

Funding source
Supported by Vice-Chancellery of Research and Technology, Shiraz University Of Medical Sciences

Expected recruitment start date
2012-11-21, 1391/09/01
Expected recruitment end date
2013-11-22, 1392/09/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Clinical Trial of Awake Nasotracheal Fiberoptic Intubation: A Comparison of Three Techniques of Conscious Sedation with Remifentanil ,Ketamin and Propofol Without Muscle Relaxants on hemodynamic Parameters in Tempro-mandibular Joint Ankylosis Surgery

Public title
Awake Nasotracheal Fiberoptic Intubation: A Comparison of Three Techniques of Conscious Sedation with Remifentanil ,Ketamin and Propofol Without Muscle Relaxants .
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria : The patients with Physical status of I and age 15 to 60 years are enrolled; Exclusion criteria : The Patients with systemic disease and or taking any medication will excluded .
Age
From **15 years** old to **60 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee Of Shiraz University Of Medical Sciences
Street address
Vice-Chancellery of Research and Technology, Shiraz University of Medical Sciences, Zand Avenue.
City
Shiraz
Postal code
71345-1978
Approval date
2012-08-20, 1391/05/30
Ethics committee reference number
03-2404

Health conditions studied

1

Description of health condition studied
Awake Nasotracheal Fiberoptic Intubation in Temporomandibular joint disorders
ICD-10 code
M24.6
ICD-10 code description
Ankylosis of joint

Primary outcomes

1

Description
Hemodynamic stability in cardiovascular patients for safe intubation
Timepoint
During the intubation procedure
Method of measurement
Blood pressure and heart rate monitoring

2

Description
Level of sedation and the patient's tolerance to the safe intubation
Timepoint
Immediately before - during - and end of Fiberoptic procedure
Method of measurement
Ramsay Sedation score (RSS)

3

Description
Speed in performing intubation
Timepoint
End of procedure
Method of measurement

minute

Secondary outcomes

1

Description
Complications during intubation
Timepoint
After the procedure and 24 hours after surgery.
Method of measurement
Direct observation by the doctor and the patient report

2

Description
Satisfaction of anesthesiologist for intubation
Timepoint
End of the procedure
Method of measurement
Rating of poor (0), moderate (1), good (2), high (3)

3

Description
Waste of time for procedure
Timepoint
End of the procedure
Method of measurement
minute

Intervention groups

1

Description
Single dose -Intravenous infusion of Remifentanil as "conscious sedation" with dose of 0.75 microgram/kg for fiberoptic intubation through the nose
Category
Treatment - Drugs

2

Description
Single dose -Intravenous infusion of Ketamin as "conscious sedation" with dose of 0.25 miligram/kg for fiberoptic intubation through the nose
Category
Treatment - Drugs

3

Description
Single dose -Intravenous infusion of Propofol as "conscious sedation" with dose of 0.5 miligram/kg for fiberoptic intubation through the nose
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shiraz Chamran Hospital
Full name of responsible person
Hamid Reza Eftekharian
Street address
Shiraz University Of Medical Sciences, Shiraz Chamran Hospital, Chamran Blvd., Shiraz
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-Chancellery of Research and Technology, Shiraz University Of Medical Sciences
Full name of responsible person
Dr. Gholamreza Hatam
Street address
Vice-Chancellery of Research and Technology, Shiraz University of Medical Sciences, Zand Avenue.
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-Chancellery of Research and Technology, Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Kamal Zarei
Position
resident of maxillofacial surgery
Other areas of specialty/work
Street address
Shiraz Chamran Hospital, Chamran Blvd., Shiraz, Iran

City
Shiraz
Postal code
71948-15644
Phone
+98 71 1648 3783
Fax
+98 62 34507
Email
paymani@hotmail.com
Web page address
www.hotmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Hamid Reza Eftekharian
Position
Assistant professor
Other areas of specialty/work
Street address
Shiraz Chamran Hospital, Chamran Blvd., Shiraz, Iran
City
Shiraz
Postal code
71948-15644
Phone
+98 71 1648 3783
Fax
+98 62 34507
Email
eftekharhr@sums.ac.ir
Web page address
www.sums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Hamid Reza Eftekharian
Position
Assistant professor
Other areas of specialty/work
Street address
Shiraz Chamran Hospital, Chamran Blvd., Shiraz, Iran
City
Shiraz
Postal code
71948-15644
Phone
+98 71 1648 3783
Fax
+98 62 34507
Email
eftekharhr@sums.ac.ir
Web page address
www.sums.ac.ir

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