

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Clinical trial of comparing the physician's satisfaction of adequacy of sedation for endoscopy in two groups of patients whose type of sedation will be chosen by the doctor or by the patient

Protocol summary

Summary

The aim of this study is to compare the physician's satisfaction of adequacy of sedation for endoscopy in two groups of patients whose type of sedation will be chosen by the doctor or by the patient. Accordingly, one hundred and forty adult patients who do not have any severe systemic disease and are referred to Imam Khomeini Hospital of Sari for diagnostic upper gastrointestinal endoscopy will be randomly assigned into two groups in order to compare the adequacy of upper GI tract endoscopy after choosing the type of sedation by either the physician or by the patient who were provided by educational pamphlets, stating the different kinds of sedation and their probable adverse effects. Finally, the satisfaction of the physician about the adequacy of sedation for completing the procedure of endoscopy will be analyzed and compared between the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201606062499N4**

Registration date: **2016-11-30, 1395/09/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-11-30, 1395/09/10

Registrant information

Name

Hafez Tirgar Fakheri

Name of organization / entity

Mazandaran University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellor for Research, Mazandaran University of Medical Sciences

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2017-01-21, 1395/11/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of comparing the physician's satisfaction of adequacy of sedation for endoscopy in two groups of patients whose type of sedation will be chosen by the doctor or by the patient

Public title

The Physician's Satisfaction of the Quality of Endoscopy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: the need for diagnostic upper gastrointestinal endoscopy Exclusion criteria: age below 18 or above 80 years; severe cardiopulmonary, renal or liver failure

Age

From **18 years** old to **80 years** old
Gender
Both
Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **140**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Patients were divided by blocked randomization.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Etics Committee of Mazandaran University of Medical Sciences
Street address
Mazandaran University of Medical Sciences, Moallem Square, Sari, Mazandaran, Iran
City
Sari
Postal code
Approval date
2014-05-29, 1393/03/08
Ethics committee reference number
H-92-33

Health conditions studied

1

Description of health condition studied

Diseases of upper digestive system which need endoscopy
ICD-10 code
K20
ICD-10 code description
Oesophagitis

2

Description of health condition studied

Diseases of upper digestive system which need endoscopy

ICD-10 code

K25

ICD-10 code description

Gastric ulcer

3

Description of health condition studied

Diseases of upper digestive system which need endoscopy

ICD-10 code

K22.7

ICD-10 code description

Barrett oesophagus

Primary outcomes

1

Description

physician's satisfaction of the adequacy of sedation for performing endoscopy

Timepoint

Immediately after completing the endoscopy

Method of measurement

questionnaire

Secondary outcomes

1

Description

Quality of endoscopy

Timepoint

during and 20 **نهدعفتس** after the endoscopy

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: The type of sedation (including intravenous Midazolam 1.5 milligram, intravenous Pethidine 12.5 milligram or general anesthesia) will be chosen by the patient after being educated by a pamphlet.

Category

Treatment - Drugs

2

Description

Control group 1: In this group, Intravenous Midazolam 1.5 milligram will be injected to the patient before performing endoscopy. The dose and/ or type of sedative may change during endoscopy according to the physician's opinion.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Dr. Hafez Fakheri

Street address

Imam Khomeini Hospital, Amir Mazandarani street,
Sari, Mazandaran

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Ahmad Ali Enayati

Street address

Mazandaran University of Medical Sciences, Moallem
Square, Sari, Mazandaran

City

Sari

Grant name**Grant code / Reference number**

10506

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Hafez Fakheri

Position

Professor; Gastroenterologist

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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