Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jun 2026

Effect of Oral Midazolam in Pain relief of patients need Nasogastric Tube insertion:A Clinical Trial Study

Protocol summary

Study aim

The effect of oral midazolam in relieving pain in the patients who need insertion of nasogastric tube(NGT); Determining and comparing the pain amount in time of NGT insertion in two groups with receiving midazolam and placebo; Determining and comparing the satisfaction in time of NGT insertion in two study groups;

Design

Study of randomised clinical trial with control group; parallel group; triple blind; Patients are divided into two groups according to a randomized computer program and then divided into case and control groups.

Settings and conduct

Triple blind researches being carried out on the patients referred to the emergency department of zanjan Mousavi and Valiasr Hospitals, which require the insertion of NGT.Twenty minutes before the insertion of the NGT, low dose of sedation (2milligram) syrup midazolam will give to the first group and the same amount of placebo syrup will be given to second group. The syrup is presented with encoding. The person who inserts NGT and Evaluator are not aware about drug type.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18 till 60 years old;pregnancy; breastfeeding; chronic obstructive pulmonary disease;decrease level of consciousness; vomiting;benzodiazepine allergy; weight below 40 kilogram; benzodiazepine contraindications;

Intervention groups

200 patients are divided into 2 groups. Twenty minutes before the insertion of NGT, low dose of sedation (2 milligram) syrup midazolam will give to the first group and the same amount of placebo syrup will be given to second group. outcomes will be observed

Main outcome variables

Evaluation of pain severity based on visual analog scale; Evaluation of patients satisfaction of nasogastric tube insertion;

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110629006922N4**
Registration date: **2019-05-28, 1398/03/07**
Registration timing: **retrospective**

Last update: **2019-05-28, 1398/03/07**
Update count: **0**

Registration date

2019-05-28, 1398/03/07

Registrant information

Name

Afsaneh Karami

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

2018-10-23, 1397/08/01

Actual recruitment end date

2019-05-20, 1398/02/30

Trial completion date

2019-05-20, 1398/02/30

Scientific title
Effect of Oral Midazolam in Pain relief of patients need Nasogastric Tube insertion:A Clinical Trial Study

Public title
Effect of Oral Midazolam in Pain relief

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
patients with age 18 - 60 years Indication for Nasogatric tube insertion (treatment - diagnostic)

Exclusion criteria:
decrease level of consciousness allergy to benzodiazepines difficulty of swalloing nausea or vomiting chronic obstructive pulmonary disease pregnancy breastfeeding hypotension (systolic blood pressure below 90) Dissatisfied to participate in the study

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **200**
Actual sample size reached: **200**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are divided into 2-person blocks based on a Random Software Allocation Software (RAS) program, then the two case groups (Midazolam receiving group) and the control group (the group receiving the placebo) will be defined in the software.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Patients are randomly divided into two groups based on RAS software. Prepared syrups with the dosage calculated from midazolam and placebo were delivered to the person responsible for the NG Tube and will be administered orally, 20 minutes before the procedure, with a mild administration dose (2 mg). Containers containing midazolam and placebo are pre-coded so that the relevant assistant, patient and NG Tube employs the contents of the dishes. And the placebo is used in terms of color, odor, and appearance of the drug.

Placebo
Used

Assignment
Parallel

Other design features
Due to the presence of pain during insertion of NG Tube and its intolerance in many patients, and the lack of a positive clinical response to thrombocytopenia with lidocaine, as well as the side effects and limitations related to intravenous ketamine and midazolam, we decided This study was conducted to evaluate the effects of oral midazolam in relieving pain in patients requiring ease of administration of NG Tube.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Zanjan University of Medical Sciences

Street address
Valiasr Square; Sheikh Fazlollah Noori Highway; Educational & Therapeutic Valiasr Center

City
Zanjan

Province
Zanjan

Postal code
4515777977

Approval date
2018-10-15, 1397/07/23

Ethics committee reference number
IR.ZUMS.REC.1397.187

Health conditions studied

1

Description of health condition studied
Effect of oral midazolam on Reduce pain in the time of nasogastric insertion

ICD-10 code
Y47

ICD-10 code description
Sedatives, hypnotics and antianxiety drugs

Primary outcomes

1

Description
Pain sensation in visual analog score

Timepoint
Time of nasogastric insertion

Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description

Satisfaction with Nasogastric tube insertion

Timepoint

After nasogastric tube insertion

Method of measurement

Visual analogue scale

Intervention groups

1

Description

Intervention group: Midazolam receiving group; Midazolam syrup, which was made by professors of Pharmacology Department of Tabriz University of Medical Sciences. This syrup is given orally to a patient at a dose of 2 mg 20 minutes before the nasogastric tube is inserted. After insertion, it will be questioned about the severity of pain and the satisfaction of the insertion of this tube.

Category

Treatment - Drugs

2

Description

Control group: Group receiving placebo. Placebo syrup was also made by professors of the Pharmacology Department of Tabriz University of Medical Sciences. The placebo syrup is quite similar to midazolam and its mode of administration is similr midazolam. This syrup is given orally to a patient at a dose of 2 mg 20 minutes before the nasogastric tube is inserted. After insertion, it will be questioned about the severity of pain and the satisfaction of the insertion of this tube.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emergency department of Educational & Therapeutic Hospital of Valiasr; Zanjan

Full name of responsible person

Ala Rastin

Street address

Zanjan; Valiasr Square; Sheikh Fazlollah Noori Highway; Valiasr Medical Education Center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Alireza Shoghli

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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

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Ala Rastin

Position

Emergency Medicine Assistant

Latest degree

Medical doctor

Other areas of specialty/work

Emergency Medicine

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Person responsible for scientific inquiries

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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
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The whole data after Unidentifiable of patients, will be converted into the article and we try to published it in a reliable Journal
When the data will become available and for how long
All data will be released without time limitation.
To whom data/document is available
Results will be available for all groups.
Under which criteria data/document could be used
Data will be available to interested researchers without limitations.
From where data/document is obtainable
In order to receive the data, during communication with the responsible scientific officer, the requested information will be provided to the applicants through his email.
What processes are involved for a request to access data/document
With request for Information, it will be sent by email as soon as possible.
Comments