Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of oral gabapentin versus oral acetaminophen on controlling of pain after chest tube insertion: a double-blind randomized clinical trial

Protocol summary

Study aim
To assess the effect of oral gabapentin versus oral acetaminophen on controlling of pain after chest tube insertion

Design
This is a double-blind randomized clinical trial with control group, phase III, in which eligible patients will be randomly assigned through the drawing of lots to the intervention and control groups

Settings and conduct
This study will be performed in the Besat Hospital in Hamadan city on 60 eligible candidates for chest tube insertion. The patients will be randomly assigned to the intervention and control groups through the drawing of lots. This trial will be double-blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18 to 60 years Candidate for chest tube insertion Exclusion criteria: Pregnancy Body mass index greater than 30 Receiving opioid medications Addiction to opium Renal of liver failure

Intervention groups
Intervention group: Oral gabapentin tablet 1200 mg one hour before chest tube insertion and then 600 mg three times daily for at most one week Control group: Oral acetaminophen tablet 1000 mg one hour before chest tube insertion and then 1000 mg three times daily for at most one week

Main outcome variables
Primary outcome: Pain healing Secondary outcome: Possible cardiopulmonary complication

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N429**
Registration date: **2022-05-23, 1401/03/02**
Registration timing: **prospective**
Last update: **2022-05-23, 1401/03/02**
Update count: **0**

Registration date
2022-05-23, 1401/03/02

Registrant information

Name
Jalal Poorolajal

Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-06-22, 1401/04/01

Expected recruitment end date
2022-08-24, 1401/06/02

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of oral gabapentin versus oral acetaminophen on controlling of pain after chest tube insertion: a double-blind randomized clinical trial

Public title
Effect of oral gabapentin versus oral acetaminophen on controlling of pain after chest tube insertion

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 60 years Candidate for chest tube insertion

Exclusion criteria:

Pregnancy Body mass index greater than 30 Receiving opioid medications Addiction to opium Renal of liver failure

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention" on one sheet and "control" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The shape of the medications will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention.. Thus, the trial will be run as double-blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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Postal code

6517838695

Approval date

2022-05-07, 1401/02/17

Ethics committee reference number

IR.UMSHA.REC.1401.126

Health conditions studied

1

Description of health condition studied

Pneumothorax

ICD-10 code

J93.11

ICD-10 code description

Primary spontaneous pneumothorax

Primary outcomes

1

Description

Pain healing

Timepoint

Immediately after chest tube insertion and 12, 24, 48, and 72 hours after that

Method of measurement

Using Visual Analog Scale (VAS)

Secondary outcomes

1

Description

Possible cardiopulmonary complication

Timepoint

Immediately after chest tube insertion and 12, 24, 48, and 72 hours after that

Method of measurement

With taking history and clinical examination

Intervention groups

1

Description

Intervention group: Oral gabapentin tablet 1200 mg one hour before chest tube insertion and then 600 mg three times daily for at most one week

Category

Treatment - Drugs

2

Description

Control group: Oral acetaminophen tablet 1000 mg one hour before chest tube insertion and then 1000 mg three

times daily for at most one week

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital in Hamadan city

Full name of responsible person

Dr Mehrshad Sedigh

Street address

Besat Hospital, Shahed Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Dr Mehrshad Sedigh

Position

Resident of Surgery

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Person responsible for updating data

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Professor of Epidemiology

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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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