Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Subcutaneous octreotide therapy for malignant pleural effusion after pleurodesis with talc powder: A placebo-controlled, triple-blind, randomized trial

Protocol summary

Study aim

In this study, we intended to investigate the therapeutic effects and safety of octreotide in patients with MPE undergoing pleurodesis with talc powder.

Design

A placebo-controlled, triple-blind, randomized trial

Settings and conduct

It was performed at the thoracic surgery ward of Imam Khomeini Hospital, Tehran University of Medical Sciences, Tehran, Iran from March 2020 to March 2021

Participants/Inclusion and exclusion criteria

Included participants were patients with confirmed cancer and MPE that were candidates for pleurodesis with talc using pleuroscopy due to the need for repeated pleural drainage. MPE was diagnosed based on thoracocentesis and cytological examination of pleural fluid. Other inclusion criteria were 1) age>18 years old, 2) chest tube discharge>150 cc/day, and 3) estimated survival>6 months. Exclusion criteria were 1) lung entrapment, 2) concomitant chemotherapy or radiotherapy, 3) treatment with Warfarin, 4) uncontrolled diabetes mellitus, 5) cholestasis, 6) pregnancy, and 7) sensitivity to octreotide.

Intervention groups

A pleural catheter was implanted for all patients. Patients in the octreotide group received 50-microgram subcutaneous injections of octreotide acetate (Novartis, Switzerland) three times/day for up to 5 days prior to the pleurodesis. When the chest tube discharge declined to less than 150 cc per day, the patient underwent pleurodesis with talc using pleuroscopy.

Main outcome variables

The primary outcome measures of this study were the amount of discharge from the chest tube before and after pleurodesis and the length of hospital stay.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210915052492N1**
Registration date: **2021-10-11, 1400/07/19**
Registration timing: **retrospective**

Last update: **2021-10-11, 1400/07/19**
Update count: **0**

Registration date

2021-10-11, 1400/07/19

Registrant information

Name
Matin Vahedi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 2221 4676
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h-sanjarimoghaddam@student.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-01, 1398/12/11

Expected recruitment end date

2021-03-01, 1399/12/11

Actual recruitment start date

2020-03-01, 1398/12/11

Actual recruitment end date

2021-03-01, 1399/12/11

Trial completion date

2021-03-01, 1399/12/11

Scientific title
Subcutaneous octreotide therapy for malignant pleural effusion after pleurodesis with talc powder: A placebo-controlled, triple-blind, randomized trial

Public title
Subcutaneous octreotide therapy for malignant pleural effusion after pleurodesis with talc powder: A placebo-controlled, triple-blind, randomized trial

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with cancer and malignant pleural effusion Chest tube discharge>150 cc/day Estimated survival>6 months
Exclusion criteria:

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **46**
Actual sample size reached: **46**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients were randomized and allocated into two equal groups with a ratio of 1:1 and a block size of 4. A specific random code was created using Microsoft Office Excel and given to each patient.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Allocated drugs were presented by these codes, so their relationships were kept confidential and were not revealed until the end of the study. Distinct individuals performed randomization, assessment, drug administration, and data entry. Octreotide and placebo ampules were indistinguishable regarding their shape and color. The patients, researchers, and statisticians were blinded to drug allocations.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
The ethics committee of Tehran University of Medical Sciences
Street address
Tehran university of medical sciences, Poursina St, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1419783151

Approval date
2021-03-03, 1399/12/13

Ethics committee reference number
IR.TUMS.IKCH.REC.1399.498

Health conditions studied

1

Description of health condition studied
Malignant pleural effusion

ICD-10 code
J91.0

ICD-10 code description
Malignant pleural effusion

Primary outcomes

1

Description
The amount of discharge from the chest tube before and after pleurodesis

Timepoint
Before and after intervention

Method of measurement
Chest tube

Secondary outcomes

1

Description
Hospital stay

Timepoint
After intervention

Method of measurement
Days

Intervention groups

1

Description

Intervention group: Patients in the octreotide group received 50-microgram subcutaneous injections of octreotide acetate (Novartis, Switzerland) three times/day for up to 5 days prior to the pleurodesis. When the chest tube discharge declined to less than 150 cc per day, the patient underwent pleurodesis with talc using pleuroscopy.

Category

Treatment - Drugs

2

Description

Control group: Patients in the placebo group underwent the exact treatment and surgery protocols but received subcutaneous injections of NaCl 0.9% instead of octreotide.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital complex

Full name of responsible person

Matin Vahedi

Street address

Imam Khomeini hospital complex, Qarib St, Tehran, Iran

City

Tehran

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1419783151

Phone

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dr.matinvahedi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Research department of TUMS

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Matin Vahedi

Position

Cardiothoracic surgery fellowship

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Position

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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
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available