Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

A study to evaluate the effect of Montelukast tablets on respiratory complications in patients with multiple trauma suffering from lung injury; a double blind randomized clinical trial

Protocol summary

Study aim

To determine the effect of Montelukast tablets on respiratory complications detected in patients with multiple trauma suffering from lung injury

Design

Phase 2 clinical trial with control group, with parallel, double blind and randomized groups (En block randomization - Individual Random Unit- Using a sealed envelope). One group receives medication (Montelukast) and the other Group recieves placebo. The sample size is 60 patients in both groups.

Settings and conduct

The study site is Shahid Rajaee trauma hospital of Shiraz. Patients who have inclusion criteria, will be randomly divided into either drug or placebo groups. Standard care will be provided for patients and they will follow for 7 days. Computed tomography is performed on the day of entry and on the seventh day and results are recorded. The study is blinded to participants, carers, evaluators, and analyzers.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients with blunt multiple trauma and at least 3 fractured ribs, Patients with blunt multiple trauma and lung contusion detected in CT scan performed on arrival, Exclusion Criteria: Patients younger than 16 years, Patients with penetrating trauma, Patients with history of cardiopulmonary disease, Patients with history of hypersensitivity to Montelukast, Patients who will not sign the informed written consent

Intervention groups

Intervention group: Airokast® (Montelukast -as sodium- Abidi company) 10 mg Orally, Once daily for 7 days
Control group: Placebo pills (Produced in the Faculty of Pharmacy, Shiraz University of Medical Sciences) the same as Monteleukast tablets, Orally, Once daily for 7 days

Main outcome variables

CT scan findings about volume and location of lung contusion; Pulmonary complication like acute lung injury, acute respiratory distress syndrome and pneumonia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190719044270N1**
Registration date: **2019-11-08, 1398/08/17**
Registration timing: **registered_while_recruiting**

Last update: **2019-11-08, 1398/08/17**
Update count: **0**

Registration date

2019-11-08, 1398/08/17

Registrant information

Name

Ali Taheri Akerdi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 3625 4206

Email address

ata110iran@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A study to evaluate the effect of Montelukast tablets on respiratory complications in patients with multiple trauma suffering from lung injury; a double blind randomized clinical trial

Public title
The effect of Montelukast on respiratory complications detected in patients with multiple trauma and lung injury
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with blunt multiple trauma and at least 3 fractured ribs Patients with blunt multiple trauma and lung contusion detected in CT scan performed on arrival
Exclusion criteria:
Patients younger than 16 years Patients with penetrating trauma Patients with history of cardiopulmonary disease Patients with history of hypersensitivity to Montelukast Patients who will not sign the informed written consent
Age
From **16 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
block randomization - Individual Random Unit- Using a sealed envelope. We Use "Random allocation Software" to allocate 60 patients into Two Groups randomly by using blocks size of 4. These random numbers and drugs (placebo or true medication) are placed in envelopes and then, as each patient arrives, an envelope is opened and treatment is applied to each individual. Obviously, the drug in the envelope is also not detectable for staffs in terms of being a placebo or true medication.
Blinding (investigator's opinion)
Double blinded
Blinding description
The placebo tablets will be provided in the same color, shape, size, and weight as the Monteleukast tablets .They will be packaged in the same packages, too. A unique number will be written on each package (Monteleukast or placebo). This number and its corresponding contents (Monteleukast or placebo) will be recorded by the researcher. The numbered packages will be provided to the patient's nurse. The nurses will be asked to record the numbers on the package in the relevant form after being used by the patient and obtaining the medical, clinical and laboratory data. Consequently, the nurses, staffs, and patients will only encountered the numbers on the packages but not their content. After removing the participant name from the CT images, a unique number will be lithographed on each image. As a result, the radiologist will be unaware of the patient's name and the therapy. The Radiologist will record the number after reporting the images on the report form. Only the researcher will have access to the corresponding names and numbers. After the therapy course a new CT scan will be done. The patients names will be removed in the first step .A new number, independent of the numbers written on the pre-treatment images, will be lithographed on the new images. Consequently, the radiologist will be blind to therapy effect in the follow-up images. Finally, the data will be entered in a statistical analysis software. The case and control groups will be labeled as group A and B. Afterward, the statistical information will be sent to the statistical specialist, who is blind to case and control group.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee affiliated to Baqiyatallah University of Medical Sciences
Street address
Bagheit_Allah Medical School, South Sheykh Bahaee St, Molasadra St, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1435916471
Approval date
2019-07-08, 1398/04/17
Ethics committee reference number
IR.BMSU.REC.1398.112

Health conditions studied

1

Description of health condition studied
Contusion of lung

ICD-10 code
S27.32
ICD-10 code description
Contusion of lung

2

Description of health condition studied
Multiple fractures of ribs
ICD-10 code
S22.4
ICD-10 code description
Multiple fractures of ribs

3

Description of health condition studied
Acute respiratory distress syndrome
ICD-10 code
J80
ICD-10 code description
Acute respiratory distress syndrome

4

Description of health condition studied
Pneumonia
ICD-10 code
B95.3
ICD-10 code description
Streptococcus pneumoniae as the cause of diseases classified elsewhere

5

Description of health condition studied
Pulmonary embolism
ICD-10 code
I26
ICD-10 code description
Pulmonary embolism

Primary outcomes

1

Description
Lung contusion
Timepoint
on day 0 and 7
Method of measurement
Chest CT-scan

2

Description
Acute Lung Injury
Timepoint
on day 7
Method of measurement
Chest CT-scan

3

Description
Acute Respiratory Distress Syndrome
Timepoint
on day 7
Method of measurement
Chest CT-scan

4

Description
Pulmonary Emboli
Timepoint
on day 7
Method of measurement
Chest CT angiography

5

Description
Pneumonia
Timepoint
on day 7
Method of measurement
Chest CTscan

Secondary outcomes

1

Description
C reactive Protein
Timepoint
day 0 and 3
Method of measurement
Serum agglutination test

2

Description
Procalcitonin
Timepoint
day 3
Method of measurement
Blood level of procalcitonin

3

Description
Length of ICU stay
Timepoint
Discharge from ICU
Method of measurement
counting ICU admission days

4

Description
Days underwent ventilator assisted respiration
Timepoint
on discharge
Method of measurement

counting the days underwent ventilator assisted respiration

Intervention groups

1

Description
Intervention group: Airokast® (Montelukast -as sodium- Abidi company) 10 mg Orally, Once daily for 7 days
Category
Prevention

2

Description
Control group: Placebo pills (Produced in the Faculty of Pharmacy, Shiraz University of Medical Sciences) like real drug, Orally, Once daily for 7 days
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shiraz Rajaei Hospital
Full name of responsible person
Ali Taheri Akerdi
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Trauma Research Center, Rajaee Hospital, Chamran Avenue, Shiraz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
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heydari.dr@gmail.com
Web page address
https://www.bmsu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Ali Taheri Akerdi
Position
General Surgeon - Researcher
Latest degree
Specialist
Other areas of specialty/work
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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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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 baseline, clinical, and outcome measures databases would be available in SPSS format after publication of the study

When the data will become available and for how long

The data will be available immediately after publication of the study

To whom data/document is available

The data would be available to the readers of published article through the journals website

Under which criteria data/document could be used

There is not limitation for accessing the study data after publication

From where data/document is obtainable

The database would be available as an appendix to the published article

What processes are involved for a request to access data/document

The database would be available as an appendix to the published article. The availability would be according to the publishers policy

Comments