Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of the Effects of Baricitinib in Acute Respiratory Distress Syndrome (ARDS) Patients: A Randomized Clinical Trial

Protocol summary

Study aim

Evaluation of the Effects of Baricitinib in Acute Respiratory Distress Syndrome (ARDS) Patients

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 40 patients. simple random allocation method will be used for randomization.

Settings and conduct

This double-blind, placebo-controlled clinical trial will be conducted in Tabriz Imam Reza Hospital in patients with acute respiratory syndrome who consent to enter the study.40 patients are divided into two groups (twenty people in each group) receiving medicine and placebo using systematic random method and computer numbers. Baricitinib is administered at a dose of 4 mg/day and an oral placebo according to the same schedule as the active drug. All patients will receive standard supportive care in the hospital.The participants and the researcher and data analyst will be blinded in this study.

Participants/Inclusion and exclusion criteria

Patients were included in the study if they met the following criteria: adults with mild to moderate Acute Respiratory Distress Syndrome (ARDS) who require oxygen therapy ($PaO_2/FiO_2 < 300$ mmHg) and are capable of long-term supine position. Exclusion criteria include pregnancy, age below 18 and above 80 years, and concomitant diseases (infection/suppression of the immune system, human immunodeficiency virus, liver, kidney and/or acquired immunodeficiency syndrome

Intervention groups

Intervention group: Baricitinib of Nano Daro Alvand Company will be prescribed at a dose of 4 mg daily orally for 14 days or until discharge from the hospital. In the control group, an oral placebo will be administered according to the same schedule as the active drug.

Main outcome variables

number of days without ventilator; The duration of hospitalization and the patient's outcome are considered as the main outcome of this study.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231017059748N3**
Registration date: **2023-12-14, 1402/09/23**
Registration timing: **registered_while_recruiting**

Last update: **2023-12-14, 1402/09/23**
Update count: **0**

Registration date

2023-12-14, 1402/09/23

Registrant information

Name

Hadi Hamishehkar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3337 2250

Email address

hamishehkar@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-06, 1402/09/15

Expected recruitment end date

2024-12-05, 1403/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the Effects of Baricitinib in Acute Respiratory Distress Syndrome (ARDS) Patients: A Randomized Clinical Trial

Public title
Evaluation of the Effects of Baricitinib in Acute Respiratory Distress Syndrome (ARDS) Patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Adults with mild to moderate Acute Respiratory Distress Syndrome (ARDS) who require oxygen therapy (PaO2/FiO2 < 300 mmHg) Patients who are capable of long-term supine position

Exclusion criteria:
Pregnancy Age below 18 and above 80 years concomitant diseases (infection/suppression of immune system, human immunodeficiency virus, liver, kidney and/acquired immunodeficiency syndrome)

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, simple random allocation method will be used. In this method, a list of numbers from 1 to 40 will be prepared. In this list, numbers are randomly divided. Depending on the time of the patient's visit, one of these numbers will be assigned to the patient, and based on the created list and being even or odds, the patients will be assigned to the intervention and the control groups. The intervention group will be even numbers and the control group will be odd numbers. Then, the sealed envelope method will be used for concealment. In this way, each number will be written on a card and then placed inside the envelopes. We will glue the lids of the envelopes and put them in the boxes. for Participants in order of entering, one of the envelopes will be opened and the assigned group to that participant will be determined.

Blinding (investigator's opinion)
Double blinded

Blinding description
Drug and placebo are blindly coded while they are manufactured uniform and the participant and clinical caregiver will be unaware of their content. In addition, The results of the study, without mentioning the type of treatment performed on the patient, with headings A and B will be provided to the analyst to evaluate the consequences.So, these people will be blinded.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee Of Tabriz University Of Medical Sciences

Street address
Third Floor, Nnmber 2 Central Building, Golgasht Street

City
Tabriz

Province
East Azarbaijan

Postal code
5166616471

Approval date
2023-08-13, 1402/05/22

Ethics committee reference number
IR.TBZMED.PHARMACY.REC.1402.030

Health conditions studied

1

Description of health condition studied
Acute respiratory distress syndrome

ICD-10 code
U04.9

ICD-10 code description
Severe acute respiratory syndrome [SARS], unspecified

Primary outcomes

1

Description
High-flow nasal oxygen therapy and noninvasive ventilation

Timepoint
Length of hospital stay

Method of measurement
observation

2

Description

Invasive mechanical ventilation

Timepoint

Length of hospital stay

Method of measurement

observation

Secondary outcomes

1

Description

O2 saturation

Timepoint

Twice a day (morning and evening) and while receiving non-invasive ventilation until the patient is hospitalized in the intensive care unit.

Method of measurement

Pulse oximeter

2

Description

Duration of stay in intensive care unit

Timepoint

From the time of admission to the intensive care unit until the time of discharge or death

Method of measurement

Observation

3

Description

The number of days without a ventilator

Timepoint

Length of hospital stay

Method of measurement

Observation

4

Description

Duration of recovery

Timepoint

Length of hospital stay

Method of measurement

Observation

5

Description

Paient outcom

Timepoint

Length of hospital stay

Method of measurement

Observation

Intervention groups

1

Description

Intervention group: Baricitinib of Nano Daro Alvand Company will be prescribed at a dose of 4 mg daily orally for 14 days or until discharge from the hospital. Patients whose glomerular filtration rate is estimated to be less than 60 ml/min will receive baricitinib. They will receive a dose of 2 mg once a day.All patients will be received standard supportive care in the hospital, including fluid restriction, mechanical ventilation, use of PEEP, inhaled vasodilators (not used routinely and only in case of treatment failure and severe hypoxia), as well as administration of corticosteroids and supportive care.

Category

Treatment - Drugs

2

Description

Control group: Receiving baricitinib placebo, which is identical in shape, color and size, for 14 days or until discharge from the hospital All patients will be received standard supportive care in the hospital, including fluid restriction, mechanical ventilation, use of PEEP, inhaled vasodilators (not used routinely and only in case of treatment failure and severe hypoxia), as well as administration of corticosteroids and supportive care.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Educational and Medical Center

Full name of responsible person

Hadi Hamishehkar

Street address

Imam Reza Educational and Medical Center, in front of the central organization of the University, Golgasht St., Tabriz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research,Tabriz University Of Medical Sciences

Full name of responsible person

Dr.Parviz Shahabi

Street address

No. 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street, Tabriz

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5138665793

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Email
research-vice@tbzmed.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Vice chancellor for Research,Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Hadi Hamishehkar

Position
Professor

Latest degree
Specialist

Other areas of specialty/work
Medical Pharmacy

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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