

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Evaluation of the efficacy and safety of Deferasirox as adjunctive therapy for Mucormycosis: a double-blind randomized controlled clinical trial

Protocol summary

Study aim

Determination of efficacy and safety of Deferasirox as adjunctive therapy for mucormycosis

Design

Randomized Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2-3 on 40 patients, which will be randomized using block block method and WinPepi software.

Settings and conduct

This study will be performed on patients with mucormycosis in Imam Khomeini Hospital in Ahvaz and the participants (patients) and the treatment team and the analyzer will be blind during the study. At the patient level, blindness will be performed using a placebo, and the researcher will give the drug or placebo only to patients based on label A or B, without knowing the nature of A, B, and according to the randomization list.

Participants/Inclusion and exclusion criteria

Patients with Mucormycosis over the age of 18 who are not prohibited from taking Amphotericin and Deferasirox and are willing to participate in the intervention are included in the study. Patients with a high probability of death within 48 hours after enrollment or with a high probability of death due to factors not related to Mucormycosis within 30 days following enrollment, patients unable to receive enteral medication, patients who take Deferasirox for any reason at the time of screening or are allergic or intolerant to Deferasirox or Amphotericin, and patients with significant renal impairment as well as pregnant women will be excluded from the study.

Intervention groups

The control group will be given Amphotericin at a dose of 5 mg per kg plus placebo, and the intervention group will receive amphotericin at a dose of 5 mg per kg plus Deferasirox at a dose of 10 mg per kg for 28 days.

Main outcome variables

Mortality rate; Adverse events; Drug tolerance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210429051130N2**

Registration date: **2021-11-19, 1400/08/28**

Registration timing: **prospective**

Last update: **2021-11-19, 1400/08/28**

Update count: **0**

Registration date

2021-11-19, 1400/08/28

Registrant information

Name

Seyyed Mohammad Tabibzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 9367 3111

Email address

tabibzadeh.sm@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-05-22, 1401/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy and safety of Defrasirox as adjunctive therapy for Mucormycosis: a double-blind randomized controlled clinical trial

Public title

Evaluation of the efficacy and safety of Defrasirox as adjunctive therapy for Mucormycosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age greater than 18 years. Proven or probable invasive mucormycosis, as defined by modification of consensus European Organization for Research and Treatment of Cancer (EORTC)/Mycosis Study Group (MSG) criteria. In brief, proven mucormycosis is defined as: 1) histopathologic or cytopathologic examination showing broad-based, aseptate, ribbon-like hyphae consistent with Mucorales from needle aspiration or biopsy specimen, with evidence of associated tissue damage (either microscopically or unequivocally by imaging); OR 2) a positive culture result for a sample obtained by sterile procedure from normally sterile and clinically or radiologically abnormal site consistent with infection, excluding urine and mucous membranes. Probable mucormycosis is defined as: 1) an at-risk host; AND 2) positive culture, cytology, or polymerase chain reaction (PCR) test (run at a CLIA-certified clinical microbiology laboratory) from sputum, bronchoalveolar lavage (BAL), endoscopy/colonoscopy, or sinus aspirate/biopsy; AND 3) 1 major or 2 minor clinical criteria.

Exclusion criteria:

High likelihood of death within the 48 h after enrollment (investigator's discretion). High likelihood of death due to factors unrelated to mucormycosis (e.g. due to uncontrolled and/or relapsed malignancy, severe graft versus host disease, other underlying diseases, etc.) within 30 days following enrollment (investigator's discretion). Patient unable to receive enteral medication (oral or via feeding tube). Patient is already taking deferasirox therapy for any reason at the time of screening. Patient is allergic to or intolerant of deferasirox or Amphotricin. Patient has significant renal dysfunction at the time of screening, defined as serum creatinine of > 3 mg/dL or a calculated creatinine clearance of < 30 ml/min (by the Cockcroft-Gault formula: $(140 - \text{age (yrs)}) * \text{wt (kg)}) * 0.85$ (for females) / $(72 * \text{serum creatinine (mg/dL)})$). Patient has significant hepatic dysfunction at the time of screening, defined as BOTH an AST or ALT > 10 times the upper limit of normal, AND a direct (not total) bilirubin > 5 times the upper limit of normal. Women of child-bearing potential (those with menses within the last year) with a positive serum pregnancy test.

Age

From 18 years old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Assignment of patients to treatment groups is done by randomized block method using 4 blocks, which are selected from patients diagnosed with Mucormycosis after reviewing the inclusion and exclusion criteria. Unit of randomization is individual. Randomization is done using a table of random numbers and to generate random sequences a computer will be used. For concealing treatment allocation, the list of treatments are placed in the enclosed and numbered (to maintain order of sequences) envelopes. Randomization or random assignment of patients to each treatment group will be done by randomized block method using 4 blocks by winpepi 11.4 software. Subjects were randomly divided into two groups based on the method of quadruple random blocks.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants (patients) and the treatment team and the analyzer are blind during the study. At the patient level, blindness will be performed using a placebo so that one group will be given Deferasirox and the other group will be given a placebo. , and they will not know which one they are given. . The researcher is only on the basis of label A or B , without knowing the nature of A, B and according to the randomization list, they give patients drugs or placebo.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jondishapur University of Medical Sciences

Street address

Iran- Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

1579461357

Approval date

2021-11-02, 1400/08/11

Ethics committee reference number

IR.AJUMS.REC.1400.489

Health conditions studied**1****Description of health condition studied**

Mucormycosis

ICD-10 code

B46.1

ICD-10 code description

Rhinocerebral mucormycosis

Primary outcomes**1****Description**

Mortality

Timepoint

At the end of study

Method of measurement

Mortality rate

2**Description**

Adverse Events

Timepoint

At all stages of treatment and hospitalization and at the end of the study

Method of measurement

National Cancer Institute-Common Terminology Criteria for Adverse Events (NCI-CTCAE) Version 5.0

3**Description**

Drug tolerance

Timepoint

Daily

Method of measurement

History

Secondary outcomes**1****Description**

Admission period

Timepoint

At the end of the study

Method of measurement

Calculation of the number of days of hospitalization

Intervention groups**1****Description**

Intervention group: In this group, patients will receive Amphotericin vial ,manufactured by BDR Pharmaceuticals in India, at a dose of 5 milligram per kilogram in a single dose daily intravenous plus Deferasirox tablet ,manufactured by Nano Hayat Darou in Iran, at a dose of 10 milligram per kilogram in a single dose daily and orally for 28 days.

Category

Treatment - Drugs

2**Description**

Control group: In this group, patients will receive Amphotericin vial ,manufactured by BDR Pharmaceuticals in India, at a dose of 5 milligram per kilogram in a single dose daily intravenous plus placebo tablet at a dose of 10 milligram per kilogram in a single dose daily and orally for 28 days.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Khomeini Hospital, Ahvaz, Iran

Full name of responsible person

Soheila Nikakhlagh

Street address

24 Metri Ave, Imam Khomeini hospital, Ahwaz city

City

Ahvaz

Province

Khouzestan

Postal code

6193665115

Phone

+98 61 3229 1838

Fax

+98 61 3229 1838

Email

nikakhlagh-s@ajums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Mehdi Ahmadi Moghadam

Street address

Golestan Ave, Ahwaz unevercity of medical science

City

Ahvaz

Province
Khouzestan

Postal code
6135715794

Phone
+98 61 3311 4155

Email
info@ajums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences

Full name of responsible person
Soheila Nikakhlagh

Position
Professor

Latest degree
Specialist

Other areas of specialty/work
Ear, Nose, and Throat

Street address
24 Metri Ave, Imam Khomeini hospital, Ahwaz city

City
Ahvaz

Province
Khouzestan

Postal code
6193665115

Phone
+98 61 3292 1838

Fax
+98 61 3229 1838

Email
nikakhlagh-s@ajums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person

Soheila Nikakhlagh

Position
Professor

Latest degree
Specialist

Other areas of specialty/work
Ear, Nose, and Throat

Street address
24 Metri Ave, Imam Khomeini hospital, Ahwaz city

City
Ahvaz

Province
Khouzestan

Postal code
6193665115

Phone
+98 61 3229 1838

Fax
+98 61 3229 1838

Email
nikakhlagh-s@ajums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Seyyed Mohammad Tabibzadeh

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Ear, Nose, and Throat

Street address
24 Metri Ave, Imam Khomeini hospital, ENT department, Ahwaz city

City
Ahvaz

Province
Khouzestan

Postal code
6193665115

Phone
+98 61 3229 1838

Fax
+98 61 3229 1838

Email
tabibzadeh-sm@ajums.ac.ir

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

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

Title and more details about the data/document

Information about the primary and secondary outcome after unidentified individuals will be shared.

When the data will become available and for how long

The access period will start 6 months after the results are published.

To whom data/document is available

The data will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

For research and treatment purposes

From where data/document is obtainable

Ahvaz Jundishapur University of Medical Sciences

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

Send your request to Ahvaz Jundishapur University of Medical Sciences.

Comments