Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

Evaluation of the efficacy and safety of Defrasirox 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

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Iran (Islamic Republic of)

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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 Cockroft-Gault formula: (140 - age (yrs) * wt (kg)) * 0.85 (for females) / (72 * 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
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24 Metri Ave, Imam Khomeini hospital, Ahwaz city
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Sponsors / Funding sources

1

Sponsor
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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
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
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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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

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