

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Evaluation of Intralipid efficacy for decreasing Amphotericin B-related nephrotoxicity in patients with fungal infections admitted in Amir-Alam and Imam Khomeini hospitals in Tehran during 1390-1391

Protocol summary

Summary

Objectives: Evaluation of Intralipid efficacy for decreasing Amphotericin B-related nephrotoxicity is the main goal. **Design:** This is a single-blinded randomized clinical trial study. **Setting and conduct:** Participants in this study are randomized to intervention and control groups. Patients stay in hospital during study and necessary clinical evaluations and laboratory investigations are performed for them. Baseline renal function and its variations during treatment with Amphotericin B are continuously monitored. Finally, Amphotericin B-related nephrotoxicity that has been defined as 50% increase in baseline serum creatinine to a minimum of 2mg/dL in this study along with daily changes in serum creatinine level are compared between groups and differences are statistically analyzed. **Participants:** Patients with fungal infections admitted in Amir-Alam and Imam Khomeini hospitals in Tehran during 1390-1391 who need Amphotericin B for treatment are included. baseline serum creatinine over 2mg/dL and severe liver failure or cirrhosis are major exclusion criteria. A sample size of 30 was considered for this study. **Interventions:** In both groups, 1 mg/kg daily of Amphotericin B is mixed with dextrose 5% in a concentration of 0.1 mg/mL and infused over a 4-hour period. In intervention arm, the patients additionally receive 500 mL of Intralipid 10% daily that is started within 1 hour after infusion of Amphotericin B as soon as possible. **Main outcome variable:** serum creatinine level in mg/dL

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012110411364N1**

Registration date: **2012-12-01, 1391/09/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-12-01, 1391/09/11

Registrant information

Name

Seyed Ali Dehghan Manshadi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 6119 2811

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2012-03-15, 1390/12/25

Expected recruitment end date

2012-10-22, 1391/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Intralipid efficacy for decreasing Amphotericin B-related nephrotoxicity in patients with fungal infections admitted in Amir-Alam and Imam Khomeini hospitals in Tehran during 1390-1391

Public title

Evaluation of Intralipid efficacy for decreasing Amphotericin B-related nephrotoxicity

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: patients with fungal infections admitted in Amir-Alam and Imam Khomeini hospitals in Tehran during 1390-1391 who need Amphotericin B for treatment. Exclusion criteria: pathologic hyperlipidemia; patient receiving other nephrotoxic drugs like aminoglycoside simultaneously; severe liver failure or cirrhosis; ESRD under hemodialysis or peritoneal dialysis; baseline serum creatinine over 2mg/dL; hypersensitivity to fat emulsions, egg and soya; pancreatitis

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Central building of Tehran University of Medical Sciences, Ghods cross, Keshavarz boulevard

City

Tehran

Postal code

1417653761

Approval date

2012-03-14, 1390/12/24

Ethics committee reference number

130/2525/90/3

Health conditions studied

1

Description of health condition studied

Fungal Infections

ICD-10 code

B44

ICD-10 code description

Aspergillosis

2

Description of health condition studied

Fungal Infections

ICD-10 code

B46

ICD-10 code description

Zygomycosis

3

Description of health condition studied

Fungal Infections

ICD-10 code

B49

ICD-10 code description

Unspecified mycosis

Primary outcomes

1

Description

serum creatinine level

Timepoint

baseline and daily during intervention

Method of measurement

milligram per deciliter (mg/dL) with blood sampling

Secondary outcomes

1

Description

serum potassium level

Timepoint

baseline and daily during intervention

Method of measurement

milliequivalent per liter (mEq/L) with blood sampling

Intervention groups

1

Description

In intervention group, 1 milligram per kilogram of Amphotericin B is mixed with dextrose 5% in a concentration of 0.1 milligram per milliliter and infused over a 4-hour period daily. Treatment days with Amphotericin B depend on type of fungal infection. Then, 500 milliliter of Intralipid 10% is also infused daily

that is initiated during 1 hour after Amphotericin B administration as soon as possible. Treatment days with Intralipid and Amphotericin B are equivalent.

Category

Treatment - Other

2**Description**

In control group, 1 milligram per kilogram of Amphotericin B is mixed with dextrose 5% in a concentration of 0.1 milligram per milliliter and infused over a 4-hour period daily. Treatment days with Amphotericin B depend on type of fungal infection.

Category

Treatment - Other

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

Imam Khomeini Hospital

Full name of responsible person

Seyed Ali Dehghan Manshadi M.D., resident of infectious diseases

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2**Recruitment center****Name of recruitment center**

Amir-Alam Hospital

Full name of responsible person

Mehrdad Hasibi M.D., Associate professor of infectious diseases

Street address

Saadi street, Islamic Revolution avenue

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

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotouhi

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Central building of Tehran University of Medical Sciences, Ghods cross, Keshavarz boulevard

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Tehran

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, Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty