Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Determination of Voriconazole Plasma Concentration by HPLC Technique and Evaluating Its Association with Clinical Outcome and Adverse Effects in Patients with Invasive Aspergillosis

Protocol summary

Study aim

Determination of Voriconazole Plasma Concentration by high performance liquid chromatography (HPLC) Technique and Evaluating Its Association with Clinical Outcome and Adverse Effects in Patients with Invasive Aspergillosis

Design

This is a clinical trial which was performed on 24 patients with invasive aspergillosis and were eligible for inclusion in the study.

Settings and conduct

This study was done in Dr. Masih Daneshvari Hopital. For all patients, sex, age, weight, route of administration, underlying diseases, clinical outcome, adverse effects, and lab test were recorded. For each patient, plasma sample were collected under steady-state condition and analyzed using a validated high performance liquid chromatography method.

Participants/Inclusion and exclusion criteria

Patients 18 years old and older who initiated the oral or intravenous voriconazole for possible, probable or proven invasive aspergillosis were included in the study. Exclusion criteria were history of allergy or severe reaction to azoles; aspergilloma or allergic bronchopulmonary aspergillosis; concomitant use of carbamazepine, efavirenz, rifampin, sirolimus or Ergot alkaloids; chronic invasive aspergillosis with duration of symptoms for more than 4 weeks; severe liver dysfunction (total bilirubin, , alanine transaminase (ALT), aspartate aminotransferase (AST), or alkaline phosphatase (ALP) more than 3 times the upper limit of normal); and receiving combination of antifungal therapy.

Intervention groups

Voriconazole was administered as a loading dose of 6 mg per Kg two times daily and maintenance dose of 4 mg per Kg two times daily.

Main outcome variables

Voriconazole plasma concentration, adverse effects, and outcome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151227025726N19**
Registration date: **2020-06-16, 1399/03/27**
Registration timing: **retrospective**

Last update: **2020-06-16, 1399/03/27**
Update count: **0**

Registration date

2020-06-16, 1399/03/27

Registrant information

Name

Farzaneh Dastan

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 270 5933

Email address

f_dastan@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-21, 1396/09/30

Expected recruitment end date

2019-02-19, 1397/11/30

Actual recruitment start date

2017-12-21, 1396/09/30

Actual recruitment end date

2019-02-19, 1397/11/30

Trial completion date

2019-03-20, 1397/12/29

Scientific title

Determination of Voriconazole Plasma Concentration by HPLC Technique and Evaluating Its Association with Clinical Outcome and Adverse Effects in Patients with Invasive Aspergillosis

Public title

Therapeutic Drug Monitoring of Voriconazole

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with the age of 18 years and older Patients who were initiated on oral or intravenous voriconazole for proven, probable, or possible invasive aspergillosis

Exclusion criteria:

History of allergy or severe reaction to azoles Aspergilloma or allergic bronchopulmonary aspergillosis Concomitant use of carbamazepine, efavirenz, rifampin, sirolimus or Ergot alkaloids Chronic invasive aspergillosis with duration of symptoms for more than 4 weeks Severe liver dysfunction (total bilirubin, , alanine transaminase (ALT), aspartate aminotransferase (AST), or alkaline phosphatase (ALP) more than 3 times the upper limit of normal) Receiving combination of antifungal therapy

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **24**

Actual sample size reached: **24**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of School of Pharmacy, Nursing, and Midwifery; Shahid Beheshti University of Medica

Street address

No. 2660, Vali-e Asr St., Niyayesh Junction, Tehran

City

Tehran

Province

Tehran

Postal code

141556153

Approval date

2017-12-04, 1396/09/13

Ethics committee reference number

IR.SBMU.PHNM.1396.886

Health conditions studied

1

Description of health condition studied

Invasive pulmonary aspergillosis

ICD-10 code

B44.0

ICD-10 code description

Invasive pulmonary aspergillosis

Primary outcomes

1

Description

Voriconazole plasma level

Timepoint

Minimum three days after voriconazole administration (at the time of steady-state)

Method of measurement

High performance liquid chromatography

2

Description

Evaluation of treatment success

Timepoint

7 and 14 days after treatment and at end of the study

Method of measurement

The evaluation of treatment as partial or complete success was based on clinical (fever, signs and symptoms of infection, and inflammatory markers) and radiological (CT or MRI findings) improvement or eradication of the fungal pathogen.

3

Description

Evaluation of treatment failure

Timepoint

7 and 14 days after treatment and at end of the study

Method of measurement

Failure to treatment was defined by persistent fungal

infection after more than 14 days of treatment or by progressing fungal infection defined by clinical and radiological progression, persistently positive culture results, or death due to fungal infection after more than 7 days of treatment.

Secondary outcomes

1

Description
Adverse drug reaction
Timepoint
Daily
Method of measurement
Observation and lab tests evaluation

2

Description
Death
Timepoint
At end of the study
Method of measurement
Medical Record

Intervention groups

1

Description
Intervention group: Voriconazole was administered as a loading dose of 6 mg per Kg two times daily and maintenance dose of 4 mg per Kg two times daily. For each patient, plasma sample were collected under steady-state condition and analyzed using a validated high performance liquid chromatography method.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Masih Daneshvari Hospital
Full name of responsible person
Farzaneh Dastan
Street address
Masih Daneshvari Hospital, Daar-Abad, Shahid Bahonar Ave., Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
3rd floor, School of Medicine, Evin St, Shahid Chamran Highway
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1983963113
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mpd@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Sahar Yousefian
Position
Doctor of Pharmacy
Latest degree
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Medical Pharmacy
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Person responsible for updating data

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Latest degree
Medical doctor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Title and more details about the data/document
All potential data can be shared after blinding
When the data will become available and for how long
Six months after results publishing
To whom data/document is available
Researchers working in academic institutions
Under which criteria data/document could be used
For research purposes and meta-analysis studies
From where data/document is obtainable
Dr. Farzaneh Dastan, Dr. Masih Daneshvari Hospital, Daar-Abad, Niavaran
What processes are involved for a request to access data/document
Official letter to the researchers
Comments