

# 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 Hospital. 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

##### City

Tehran

##### Province

Tehran

##### Postal code

1956944413

##### Phone

+98 21 2712 3000

##### Email

fzh.dastan@gmail.com

## 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

##### City

Tehran

##### Province

Tehran

##### Postal code

1983963113

##### Phone

+98 21 23871

##### Email

mpd@sbm.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

Medical doctor

##### Other areas of specialty/work

Medical Pharmacy

##### Street address

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

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##### Province

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saahar26@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
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Farzaneh Dastan  
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Assistant professor, Clinical Pharmacy specialist  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Medical Pharmacy  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
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Sahar Yousefian  
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**Other areas of specialty/work**  
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**Postal code**  
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**Phone**  
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**Email**  
saahar26@yahoo.com

## 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