

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### **In- Vivo Bioequivalence study of Favipiravir tablet 200mg ABIDI with brand drugs (AVIGAN 200mg, Tayoma Chemical Co. Ind. Japan) in Iranian healthy volunteers.**

#### **Protocol summary**

##### **Study aim**

In- Vivo Bioequivalence study of Favipiravir tablet 200mg ABIDI with brand drugs (AVIGAN 200mg, Tayoma Chemical Co. Ind. Japan) in Iranian healthy volunteers.

##### **Design**

Single dose, randomized, two sequences, two period crossover with a washout period.

##### **Settings and conduct**

This study will be conducted as cross-over and fasting, and on two sets of healthy volunteers. The study will be conducted in two periods of 72 hours. The interval between these two periods, which is called the wash-out time, is determined by the half-life of the drug plasma, which according to scientific sources should be at least 5 to 7 half-life of the drug in the case of the drug under study. The plan will take a week to clean up the drug, given the biological half-life of the drugs in the drug form. In the first round, candidates are divided into two groups, and the first group receives a test tablet and the second group receives a similar tablet. Blood samples will be taken by the volunteer by the technician immediately after taking the drug, and the preparation steps of the samples, including plasma separation and drug extraction, are performed to analyze the amount of drug on them.

##### **Participants/Inclusion and exclusion criteria**

24 healthy volunteers will be considered. The ages and BMIs of participant should be in the range of 18-60 and 18-28 respectively.

##### **Intervention groups**

Intervention group Single dose Favipiravir 200mg ABIDI Pharmaceutical Company with brand drugs (AVIGAN 200mg, Tayoma Chemical Co. Ind. Japan)

##### **Main outcome variables**

Determination of blood drug concentration.

#### **General information**

##### **Reason for update**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT20200105046010N30**

Registration date: **2021-04-26, 1400/02/06**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-04-26, 1400/02/06**

Update count: **0**

##### **Registration date**

2021-04-26, 1400/02/06

##### **Registrant information**

##### **Name**

Javad Shokri

##### **Name of organization / entity**

##### **Country**

Iran (Islamic Republic of)

##### **Phone**

+98 41 3661 4125

##### **Email address**

shokri.j@gmail.com

##### **Recruitment status**

**Recruitment complete**

##### **Funding source**

##### **Expected recruitment start date**

2021-03-05, 1399/12/15

##### **Expected recruitment end date**

2021-12-31, 1400/10/10

##### **Actual recruitment start date**

empty

##### **Actual recruitment end date**

empty

##### **Trial completion date**

empty

## Scientific title

In- Vivo Bioequivalence study of Favipiravir tablet 200mg ABIDI with brand drugs (AVIGAN 200mg, Tayoma Chemical Co. Ind. Japan) in Iranian healthy volunteers.

## Public title

In-vivo Bioequivalence Test of Favipiravir® tablet with brand drugs (AVIGAN® 200mg TAYOMA Chemical Ind. Co).

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

General health Body mass index(18-28) Informed consent Age(18-60)

### Exclusion criteria:

Smoking A history of cardiovascular disease A history of liver & kidney disease Pregnancy Alcohol & Drug addiction Hypersensitivity to the drug

## Age

From **18 years** old to **60 years** old

## Gender

Both

## Phase

Bioequivalence

## Groups that have been masked

*No information*

## Sample size

Target sample size: **24**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Random allocation law will be used for randomization of volunteers in this study. This method represents a large block for the total sample size, which means that a balance in the number of people assigned to each group will be obtained at the end of the study. By this method, sequences 1(subjects no: 1-12) and sequences 2 (subjects no: 13-24) will be selected by using a simple paper lottery. the first and second 12 persons will be considered as sequence 1 (Group A) and sequence 2 (Group B) respectively.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Crossover

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee, Tabriz University of Medical

Sciences

## Street address

Third floor of TUMS (Tabriz University of Medical Sciences) central building, Dneshgah St. Tabriz, Iran

## City

Tabriz

## Province

East Azarbaijan

## Postal code

5166614766

## Approval date

2020-09-28, 1399/07/07

## Ethics committee reference number

IR.TBZMED.REC.1399.668

## Health conditions studied

### 1

#### Description of health condition studied

##### ICD-10 code

##### ICD-10 code description

## Primary outcomes

### 1

#### Description

Determination of blood drug concentration.

#### Timepoint

Sampling times in this study will be 0, 1, 2, 2:30, 3, 3:20, 3:40, 4, 4:20, 4: 40, 5, 6, 8, 10, 12, 24, 48, 72 hours After prescribing the tablet.

#### Method of measurement

High Performance Liquid Chromatography with tandem mass spectroscopy detector

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Intervention group received one test drug table(Favipiravir tablet 200mg ABIDI Pharmaceutical Company). Blood samples were taken two period (72 hrs) with one week wash out time. The concentration of Favipiravir in blood samples was measured by liquid chromatography tandem mass spectroscopy method. Due to the cross-over of the plan, the candidates are placed in the intervention and control group in turn.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Control group received one test drug table

(AVIGAN 200mg, Tayoma Chemical Co. Ind. Japan ).  
Blood samples were taken from the volunteers for 72 hours at the mentioned times after drug administration and the concentration of Favipiravirin blood samples was measured by liquid chromatography with mass spectroscopy detector. Due to the crossover of the plan, the candidates are placed in the intervention and control group in turn.

**Category**

Treatment - Drugs

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

Simin Baspar Teyf Gostar Company

**Full name of responsible person**

Javad Shokri

**Street address**

No.48,Ferdos Street

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5167874434

**Phone**

+98 41 3384 2724

**Email**

Shokri.j@gmail.com

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

ABIDI Pharmaceutical Company

**Full name of responsible person**

Amir Razavian

**Street address**

8 km of Shahid Lashkari highway, Karaj special road.

Obaidi Boulevard No. 72

**City**

Tehran

**Province**

Tehran

**Postal code**

1389776363

**Phone**

+98 21 4452 2451

**Email**

info@abidi-diabetes.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Tabriz University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

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

Other

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

Tabriz University of Medical Sciences

**Full name of responsible person**

Javad Shokri

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Faculty of Pharmacy, Tabriz University of Medical Sciences.

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

Tabriz University of Medical Sciences

**Full name of responsible person**

Javad Shokri

**Position**

Professor

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
Javad Shokri  
**Position**  
Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Medical Pharmacy  
**Street address**  
Faculty of Pharmacy, Tabriz University of Medical Sciences.  
**City**  
Tabriz  
**Province**  
East Azarbaijan  
**Postal code**

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

These data are as secure between researcher and related industries

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

No - There is not a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available