

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

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No.48,Ferdos Street

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Tabriz

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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

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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

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

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Full name of responsible person

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Position

Professor

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Person responsible for updating data

Contact

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Latest degree
Ph.D.
Other areas of specialty/work
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City
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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