# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

# In-vivo Bioequivalence Study of Rimegepant 75 mg Orally Disintegrating Tablet (RIPEVA®) of The Test Drug manufactured by Dr. Abidi Pharmaceutical Company in Compared with The Reference Drug NURTEC® 75 mg

## Protocol summary

**Study aim**

In-vivo Bioequivalence Study of Rimegepant 75 mg Orally Disintegrating Tablet (RIPEVA®) of The Test Drug manufactured by Dr. Abidi Pharmaceutical Company in Compared with The Reference Drug NURTEC® 75 mg

**Design**

Bioequivalence study, Cross-over design, Single dose, Single-blinded, 24 healthy volunteers, Two period, one week wash out period, Simple randomization method will be used.

**Settings and conduct**

This single-blind, two-period crossover study was conducted on two groups of healthy volunteers at Radin Shimi Company in Tabriz. Each period lasted 48 hours, with a one -week washout interval between them. In the first period, based on computer-generated randomization, Group 1 received the reference drug while Group 2 received the test drug. In the second period, the treatments were switched. The study was single-blinded, meaning that participants were unaware whether they received the test or reference drug during either sampling period.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: Volunteers in good general health, including liver, heart, and kidney health; provision of informed consent to participate in the study; body mass index (BMI) between 18 and 30 kg/m²; and age between 18 and 55 years. Exclusion criteria: Smoking, pregnancy, history of hypersensitivity to the study drug, and alcohol consumption.

**Intervention groups**

Intervention group one receives Rimegepant 75 mg Orally Disintegrating Tablet (RIPEVA®) of the test drug manufactured by Dr.Abidi pharmacutical company in the first round, and in the second round, after one-week washout period, the drug NURTEC® 75 mg . Intervention group No.2 receives the drugs in the switched order.

**Main outcome variables**

The concentration of the drug in blood, Time to reach maximum blood concentration, Extent of absorption

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20240804062647N81**
Registration date: **2026-11-07, 1405/08/16**
Registration timing: **registered_while_recruiting**

Last update: **2026-11-07, 1405/08/16**
Update count: **0**

**Registration date**

2026-11-07, 1405/08/16

**Registrant information**

**Name**

Massoud Amanlou

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 21 6695 9067

**Email address**

amanlou@tums.ac.ir

**Recruitment status**

**recruiting**

**Funding source**

**Expected recruitment start date**

2026-10-12, 1405/07/20

**Expected recruitment end date**

2027-10-12, 1406/07/20

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

In-vivo Bioequivalence Study of Rimegepant 75 mg Orally Disintegrating Tablet (RIPEVA®) of The Test Drug manufactured by Dr. Abidi Pharmaceutical Company in Compared with The Reference Drug NURTEC® 75 mg

**Public title**

Bioequivalence Study of Rimegepant 75 mg Orally Disintegrating Tablet (RIPEVA®) by Dr. Abidi Pharmaceutical Company

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

General health (liver, heart, kidney) of volunteers Informed consent form Body mass index range (18-30) Age between18-55

**Exclusion criteria:**

Smoking Pregnancy Having a hypersensitivity to the drug Alcohol consumption

**Age**

From **18 years** old to **55 years** old

**Gender**

Both

**Phase**

Bioequivalence

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **24**
More than 1 sample in each individual
Number of samples in each individual: **30**
Blood sample

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Initially, volunteers are screened according to the study inclusion and exclusion criteria, and 24 eligible volunteers are selected. Randomization is performed using Microsoft Excel and the RAND() function. For this purpose, random values are generated for numbers 1 to 24, and the order of these numbers is randomly determined based on the generated values. Each volunteer is then assigned a unique number according to the randomization list and receives an identification card containing the assigned number. During the first study period, volunteers assigned even numbers receive the reference drug (R), while those assigned odd numbers receive the test drug (T). In the second period, the treatments are switched in a crossover manner, so that volunteers who received the reference drug in the first period receive the test drug in the second period, and vice versa. The final randomization list is kept unchanged after preparation and used for study implementation.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

This study is a single-blind (participant) clinical trial Rimegepant 75 mg Orally Disintegrating Tablet (RIPEVA®) of The Test Drug manufactured by Dr. Abidi Pharmaceutical Company and the original brand are removed from their packaging by the operator and placed in identical, coded cans. Volunteers are unaware of the type of drug or test they are receiving.

**Placebo**

Not used

**Assignment**

Crossover

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Tabriz University of Medical Sciences ethics committe

**Street address**

Vice-Chancellery for Research and Technology, 3rd Floor, Central Building No. 2, Tabriz University of Medical Sciences, Golgasht Street, Tabriz, Iran

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5174864471

**Approval date**

2026-09-21, 1405/06/30

**Ethics committee reference number**

IR.TBZMED.REC.1405.449

## Health conditions studied

### 1

**Description of health condition studied**

This study is performed on healthy volunteers.

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**

The concentration of the drug in blood

**Timepoint**

0, 0.25, 0.5, 0.75, 1, 1.5, 2, 2.5, 3, 4, 6, 8, 12, 24, 48 h after drug

**Method of measurement**

Liquid Chromatography with Mass-Mass Detector

## Secondary outcomes

### 1

**Description**
Time to reach maximum blood concentration
**Timepoint**
After intervention
**Method of measurement**
The time to reach the maximum drug concentration in blood is recorded. This is done after completing the device analysis of the samples and through the WinNonLine software developed by Phoenix Company.

### 2

**Description**
Extent of absorption
**Timepoint**
After intervention
**Method of measurement**
Calculation of area under curve of concentration -time

## Intervention groups

### 1

**Description**
Intervention group 1: Volunteers in this group will receive a single 75 mg dose of Rimegepant orally disintegrating tablet (RIPEVA), manufactured by Dr. Abidi Pharmaceutical Company (Test product), during the first study period. Following a one-week washout period, they will receive a single 75 mg dose of NURTEC ODT (Reference product) during the second study period.
**Category**
Treatment - Drugs

### 2

**Description**
Intervention group 2: Volunteers in this group will receive a single 75 mg dose of NURTEC ODT (Reference product) during the first study period. Following a one-week washout period, they will receive a single 75 mg dose of Rimegepant orally disintegrating tablet (RIPEVA), manufactured by Dr. Abidi Pharmaceutical Company (Test product), during the second study period.
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Radin laboratory
**Full name of responsible person**
Bahram Ataii
**Street address**
No.22, first floor, Moalem st., Abureihan St
**City**
Tabriz
**Province**
East Azarbaijan
**Postal code**
5154995671
**Phone**
+98 914 311 5717
**Email**
ataii.bahram@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Abidi Pharmaceutical Company
**Full name of responsible person**
Amir Razavian
**Street address**
No. 72, Abidi Boulevard, Karaj special road, 8 km of Shahid Lashkari highway
**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?**
Yes
**Title of funding source**
Abidi Pharmaceutical Company
**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**
Tehran University of Medical Sciences
**Full name of responsible person**
Massoud Amanlou
**Position**

Academic staff and full-time professor of the Faculty of Pharmacy

**Latest degree**
Ph.D.

**Other areas of specialty/work**
Medical Pharmacy

**Street address**
Faculty of Pharmacy, 16 Azar Avenue, Tehran

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## Person responsible for scientific inquiries

**Contact**

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Tehran University of Medical Sciences

**Full name of responsible person**
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## Person responsible for updating data

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## 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 researchers 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