

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 2026

### Bioequivalence study of Dapoxetine 60 mg Tablet (Pharma Chemie Pharmaceutical Company) versus Priligy 60 mg (ALZA corporation) Tablet in healthy volunteers

#### Protocol summary

##### Study aim

Bioequivalence study of Dapoxetine 60 mg Tablet (Pharma Chemie Pharmaceutical Company) versus Priligy 60 mg (ALZA corporation) Tablet in healthy volunteers

##### Design

Bioequivalence study, with control group, double-blind, randomized, on 24 volunteers, from each volunteer 20 blood samples were taken. Sealed envelope is used for randomization.

##### Settings and conduct

The subject of this biopharmaceutical and pharmacokinetic study is the location of Blood collection center of Tam Pouya Company located in Tehran. The study was blinded to the study participants by removing the drugs from the original package and placing the test and reference drugs in the same package, and the participants were not aware of the type of drug they were taking. The crossover design is such that the Iranian drug will be prescribed to the first group in the first week and to the second group in the second week. Brand medicine, on the contrary, Iranian medicine will be prescribed.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: general health (liver, heart and kidneys), body mass index (18-28), informed consent, age (50-18) Exclusion criteria: smoking, history of cardiovascular disease, history of liver disease and Renal, alcohol and drug addiction, history of allergy to Dapoxetine

##### Intervention groups

Intervention group: Receives one tablet of test drug (Dapoxetine 60 mg Tablet Pharma Chemie Pharmaceutical Company). Control group: Receives one reference medicine tablet (Priligy 60 mg tablet ALZA corporation).

##### Main outcome variables

Determination of blood concentration profile parity of

brand drug with generics

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220111053692N12**

Registration date: **2023-06-12, 1402/03/22**

Registration timing: **prospective**

Last update: **2023-06-12, 1402/03/22**

Update count: **0**

##### Registration date

2023-06-12, 1402/03/22

##### Registrant information

##### Name

Bardia Jamali

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8897 4707

##### Email address

info@tampouya.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-06-24, 1402/04/03

##### Expected recruitment end date

2023-06-28, 1402/04/07

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Bioequivalence study of Dapoxetine 60 mg Tablet (Pharma Chemie Pharmaceutical Company) versus Priligy 60 mg (ALZA corporation) Tablet in healthy volunteers

**Public title**

Bioequivalence study of Dapoxetine 60 mg Tablet (Pharma Chemie Pharmaceutical Company) versus Priligy 60 mg (ALZA corporation) Tablet in healthy volunteers

**Purpose**

Other

**Inclusion/Exclusion criteria****Inclusion criteria:**

18 to 55 years old Weight in range of 10 % proper body weight All volunteers should be in a good health condition on the basis of medical history ,physical examination , routine blood test. Possessing negative test for hepatitis B surface antigen (HBs-Ag), Antihepatitis-C antibody (anti-HCV) and anti-HIV. Gender: male

**Exclusion criteria:**

Any history of allergy to the drug or formulation components Those with known history of drug abuse. alcohol consumer or cigarette smokers. Taking medications that have drug interactions with Dapoxetine until one month before studying. Disinclination to take the test Blood donation or blood loss of more than 200 ml in the past month

**Age**

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

**Gender**

Male

**Phase**

Bioequivalence

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **24**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In order to randomly allocate people in two groups, 24 cards with numbers 1 to 24 will be used in closed envelopes that are placed in random order. After entering the study, each candidate will take an envelope, numbers 1-12 will be in group A and numbers 13-24 will be in group B. Group A will receive intervention 1 (test product) and group B will receive intervention 2 (reference product) and after the first period, the interventions of the two groups will be moved for the second period

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

This study is a Double-blind (participant) clinical trial. Dapoxetine and Priligy tablets are removed from the package by the administrator and placed in similar and

coded cans.

**Placebo**

Not used

**Assignment**

Crossover

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committees of The Institute of Pharmaceutical Sciences, Tehran University of Medical Sciences

**Street address**

Research Institute of Pharmaceutical Sciences, second floor of the old building, Faculty of Pharmacy, Enqelab Square, 16 Azar St.

**City**

Tehran

**Province**

Tehran

**Postal code**

1417613151

**Approval date**

2022-09-19, 1401/06/28

**Ethics committee reference number**

IR.TUMS.TIPS.REC.1401.053

**Health conditions studied****1****Description of health condition studied**

Bioequivalence study of Dapoxetine 60 mg Tablet (Pharma Chemie Pharmaceutical Company) versus Priligy 60 mg (ALZA corporation) Tablet in healthy volunteers

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Drug concentration in plasma samples

**Timepoint**

In times 0, 0.25, 0.5, 0.75, 1, 1.25, 1.5, 2, 2.5, 3, 4, 5, 6, 8, 10, 24, 26, 48 Hours after the start of the intervention

**Method of measurement**

chromatography

**Secondary outcomes**

empty

## Intervention groups

### 1

#### Description

Intervention group: Receives one tablet of test drug (Dapoxetine 60 mg Tablet Pharma Chemie Pharmaceutical Company). Blood samples were taken from the volunteers for 48 hours at the mentioned times after drug administration and the drug concentration in plasma samples was measured by liquid chromatography with UV detector.

#### Category

Other

### 2

#### Description

Control group: Receives one reference medicine tablet (Priligy 60 mg tablet ALZA corporation). Blood samples were taken from the volunteers for 48 hours at the mentioned times after drug administration and the drug concentration in plasma samples was measured by liquid chromatography with UV detector

#### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Tam Pouya Consulting & Research Company

##### Full name of responsible person

Bardia Jamali

##### Street address

No. 7, Navard Ave., 17 Shahrivar St., 5th Km Fat`h Highway

##### City

Tehran

##### Province

Tehran

##### Postal code

1378756411

##### Phone

+98 21 6107 4387

##### Fax

+98 21 6107 4070

##### Email

info@tampouya.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

شرکت داروسازی فارما شیمی

##### Full name of responsible person

Dr. Mohammad Reza Nikbakht

##### Street address

No. 2, 4th East Alley, 16th St., not reaching Azadegan, Kilometer 8 of Karaj special road (towards Tehran)

##### City

Tehran

##### Province

Tehran

##### Postal code

1389794581

##### Phone

+98 21 4452 5193

##### Email

info@pharmachemie.co

##### Web page address

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

شرکت داروسازی فارما شیمی

##### 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

Persons

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Tam Pouya Consulting & Research Company

##### Full name of responsible person

Bardia Jamali

##### Position

manager

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Medical Pharmacy

##### Street address

Unit 1, No. 1, Crot Building, Jahan mehr Street, Shahid Gornam Street, Fatemi Square

##### City

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##### Province

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##### Postal code

1431653941

##### Phone

+98 21 8897 4707

##### Fax

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##### Email

info@tampouya.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tam Pouya Consulting & Research Company

**Full name of responsible person**

Bardia Jamali

**Position**

manager

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Tam Pouya Consulting & Research Company

**Full name of responsible person**

Motahareh Moafi

**Position**

Office worker

**Latest degree**

Bachelor

**Other areas of specialty/work**

Office worker

**Street address**

Unit 1, No. 1, Crot Building, Jahan mehr Street, Shahid Gomonam Street, Fatemi Square

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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**

No more information

**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