

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### Bioequivalence study of vaginal progesterone suppository 400 mg of Ati Farmed pharmaceutical company compared to progesterone 400 sample manufactured by L.D. Collins&Co.,Ltd. England on healthy volunteers

#### Protocol summary

##### Study aim

The aim of these studies is to compare the absorption of two formulations of the same drug (vaginal progesterone suppository 400 mg).

##### Design

Bioequivalence studies (bioequivalence) of progesterone 400 mg vaginal suppositories manufactured by Ati Farmed pharmaceutical company compared to progesterone 400 manufactured by L.D. Collins&Co., Ltd., England includes in vivo tests after prescribing 24 healthy human volunteers with ethical approval and covered by liability insurance.

##### Settings and conduct

The study is conducted at Nik Azma Pars Alborz Company, located in Alborz Province, Mahdasht, Imam Khomeini Blvd., Azadegan Square, No. 419, Unit 3, which includes two stages (vaginal use of one 400 mg progesterone suppository in each study and in a total of 2 times) with a two-week washout period.

##### Participants/Inclusion and exclusion criteria

- A healthy non-pregnant and non-lactating female volunteer, who, while performing a pregnancy blood test before starting the study, ensures that the volunteers are not pregnant. - At the time of prescribing the drug, the volunteer should be on the 4-6th day of her menstrual cycle so that the amount of endogenous progesterone is at its minimum. - Age between 18 and 45 years. - The candidate's body mass index (BMI) must be less than 30 kg/m<sup>2</sup>. - Agree to take 10 ml of your blood for evaluation. - All candidates must be non-smokers.

##### Intervention groups

The study consists of two stages in the form of the first intervention: including the use of 400 mg progesterone vaginal suppositories manufactured by Ati Farmed Pharmaceutical Company of Iran and the second intervention: consuming the 400 mg progesterone vaginal suppositories manufactured by L.D. Collins & Co.,

Ltd. The country is England, which is done with a time interval of 2 weeks as a washing time.

##### Main outcome variables

Drug plasma concentrations

#### General information

##### Reason for update

##### Acronym

BSVP

##### IRCT registration information

IRCT registration number: **IRCT20230222057495N4**

Registration date: **2023-04-18, 1402/01/29**

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

Last update: **2023-04-18, 1402/01/29**

Update count: **0**

##### Registration date

2023-04-18, 1402/01/29

##### Registrant information

##### Name

Monireh Jalalipour

##### Name of organization / entity

Nikazma Pars Alborz company

##### Country

Iran (Islamic Republic of)

##### Phone

+98 26 3731 8748

##### Email address

info@naplab.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-04-04, 1402/01/15

##### Expected recruitment end date

2023-09-06, 1402/06/15  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Bioequivalence study of vaginal progesterone suppository 400 mg of Ati Farmed pharmaceutical company compared to progesterone 400 sample manufactured by L.D. Collins&Co.,Ltd. England on healthy volunteers

**Public title**  
Bioequivalence study of vaginal progesterone suppository 400 mg

**Purpose**  
Other

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
A healthy, non-pregnant and non-lactating female volunteer, who at the time of drug administration should be on the 4th-6th day of her menstrual cycle so that the amount of endogenous progesterone is at its minimum. Be between 18 and 45 years old. All candidates must be non-smokers. Candidate's body mass index (BMI) should be less than 30 kg/m<sup>2</sup>.

**Exclusion criteria:**  
Blood pressure lower than 90/60 mm Hg or higher than 140/90 mm Hg Smokers who use more than 10 cigarettes a day Consumption of any drugs, alcohol or tobacco products within 2 weeks before receiving the drug

**Age**  
From **18 years** old to **45 years** old

**Gender**  
Female

**Phase**  
Bioequivalence

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **24**  
More than 1 sample in each individual  
Number of samples in each individual: **36**  
n each sample, 5 cc of blood is taken from the participant at 18 time intervals. And this process is repeated twice (totally 36 samples from each person).

**Randomization (investigator's opinion)**  
Not randomized

**Randomization description**

**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

Research Institute of Pharmaceutical Sciences, Tehran University of Medical Sciences

##### Street address

Porsina Street, Tehran University of Medical Sciences, Faculty of Pharmacy, Institute of Pharmaceutical Sciences

##### City

Tehran

##### Province

Tehran

##### Postal code

1417613151

#### Approval date

2023-03-12, 1401/12/21

#### Ethics committee reference number

IR.TUMS.TIPS.REC.1401.138

## Health conditions studied

### 1

#### Description of health condition studied

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#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

C<sub>max</sub>

#### Timepoint

Once 15 minutes before the start of drug administration and then at time intervals: 0, 0.25, 0.5, 1, 1.5, 2, 3, 4, 6, 8, 10, 12, 24, 30, 48, 56 and 72 hours after administration. , will be done

#### Method of measurement

HPLC with UV detector

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

First intervention: Progesterone 400 mg vaginal suppositories manufactured by Ati Pharmed Pharmaceutical Company in Iran

**Category**

Other

**2****Description**

Second intervention: Progesterone 400 mg vaginal suppositories manufactured by L.D. Collins & Co., Ltd. England

**Category**

Other

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

Nik Azma Pars Alborz laboratory

**Full name of responsible person**

Monireh Jalalipour

**Street address**

No. 419, Imam Khomeini Boulevard, Azadegan Square

**City**

Mahdasht Karaj

**Province**

Alborz

**Postal code**

3188913179

**Phone**

+98 26 3731 8748

**Email**

info@naplab.ir

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

Ati Pharmed pharmaceutical company

**Full name of responsible person**

Behnaz Moghaddam

**Street address**

Corner of 16 St. Bucharest, Sahand Building, No. 41, 4th floor, unit

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۵۱۴۸۳۳۱۳۹

**Phone**

+98 21 8876 2210

**Email**

info@atipharmed.com

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

Yes

**Title of funding source**

Ati Pharmed 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**

Industry

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

Nik Azma Pars Alborz laboratory

**Full name of responsible person**

Monireh Jalalipour

**Position**

Responsible Pharmacist

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

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

Nik Azma Pars Alborz laboratory

**Full name of responsible person**

Monireh Jalalipour

**Position**

Responsible Pharmacist

**Latest degree**

Ph.D.

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Nik Azma Pars Alborz laboratory

**Full name of responsible person**

Monireh Jalalipour

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**Latest degree**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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