Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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/m2. - 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 Pharmed 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/m2.

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

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Cmax

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
No. 419, Imam Khomeini Boulevard, Azadegan Square
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Person responsible for scientific inquiries

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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

Position

Responsible Pharmacist

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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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