

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Comparative bioequivalence study of ASAYER® 81 mg Enteric-coated Tablet of Actoverco. and Aspirin Bayer® of BAYER as reference in 24 healthy male under fasting.

Protocol summary

Study aim

This study will be performed to compare the pharmacokinetics and in vivo parameters of ASAYER® 81 mg Enteric-coated Tablet formulation as a test product with Aspirin Bayer® 81 mg Enteric-coated Tablet formulation as a reference product and to evaluate the bioequivalence of these two formulations.

Design

Non blinded, randomized, crossover in vivo bioequivalence study in 24 healthy male under fasting condition.

Settings and conduct

In each period, volunteers will receive a single dose intervention (1 or 2) in the Farabi Clinic (Eslamshahr, Tehran). 17 blood samples were collected during 72 hours post intervention. A 7-day washout interval separated to study periods.

Participants/Inclusion and exclusion criteria

Healthy subjects (male) between 20 - 45 years of age and Body Mass Index (BMI) within 15% of normal range between 18.5 - 30 kg/m². Subjects with no significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination and laboratory evaluations. Hypersensitivity to the ASA, other NSAIDs and/or to inactive constituents. Smoking more than 10 cigarettes per day and could not tolerate cigarette cessation during each clinical period. Taking citrus fruits or their juices within 5 days before initiation of the study;

Intervention groups

Intervention group 1: ASAYER® 81 mg Enteric-coated Tablet, produced by Actoverco. is the test product. In each period, 12 of 24 subjects will be given a single oral dose of this product. Intervention group 2: Aspirin Bayer® 81 mg Enteric-coated Tablet, produced by BAYER is the reference product. In each period, 12 of 24 subjects will be given a single oral dose of this product.

Main outcome variables

Peak Plasma Concentration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180620040164N33**

Registration date: **2022-07-12, 1401/04/21**

Registration timing: **registered_while_recruiting**

Last update: **2022-07-12, 1401/04/21**

Update count: **0**

Registration date

2022-07-12, 1401/04/21

Registrant information

Name

Behzad Montaha Sangari

Name of organization / entity

Noor research and educational institute (Tavan)

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-02, 1401/04/11

Expected recruitment end date

2022-07-16, 1401/04/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative bioequivalence study of ASAYER® 81 mg Enteric-coated Tablet of Actoverco. and Aspirin Bayer® of BAYER as reference in 24 healthy male under fasting.

Public title

Comparative in vivo evaluation of 2 Aspirin 81 mg Enteric-coated Tablet formulations.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Healthy subjects (male) between 20 – 45 years of age and Body Mass Index (BMI) within 15% of normal range between 18.5 - 30 kg/m². Subjects with no significant diseases or clinically significant abnormal findings during screening, medical history, clinical examination and laboratory evaluations. Subjects that have normal vital signs. Subjects who agree with patient consent form.

Exclusion criteria:

Hypersensitivity to the ASA, other NSAIDs and/or to inactive constituents. Smoking more than 10 cigarettes per day and could not tolerate cigarette cessation during each clinical period. Taking citrus fruits or their juices within 5 days before initiation of the study; Any vaccination within 28 days and administration of any biologics within 4 months before initiation of the study. Subjects who has used any drug including prescription or Over-The-Counter (OTC) drugs within 7 days prior to the start of the study and might need drug intake during study period. History of alcohol or drug abuse within 2 years before the start of the study. Heavy drinker of caffeine, grapefruit juice or caffeinated drinks or who are on special diet (such as vegetarians) or do exertional physical activity. A history of difficulty with donating blood or donation of more than 500 ml blood within 7 days prior to the start of the study.

Age

From **20 years** old to **45 years** old

Gender

Male

Phase

Bioequivalence

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization schedule will be generated with <https://www.sealedenvelope.com/simple-randomiser/v1/lists>. A 2*2 block randomization list is created. We have 12 blocks and within each two volunteer's number (allocated after screening) for all 24 volunteers. According to this list, a treatment sequence of Test/Reference or Reference/Test will be given to each

volunteer.

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 of School of Pharmacy and Nursing & Midwifery- Shahid Beheshti University of Medica

Street address

Niayesh Highway, Valiasr Ave, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1996835113

Approval date

2021-08-10, 1400/05/19

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1400.111

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

Cardiovascular or cerebrovascular disease

ICD-10 code

I99

ICD-10 code description

Other and unspecified disorders of circulatory system

Primary outcomes**1****Description**

Peak Plasma Concentration (C_{max})

Timepoint

17 blood samples will be withdrawn pre-dose and at 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 9, 10, 12, 24, 48 and 72 hours after intervention.

Method of measurement

Using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA)

Secondary outcomes

1

Description

AUC (Area Under the Concentration-Time Curve)

Timepoint

17 blood samples will be withdrawn pre-dose and at 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8, 9, 10, 12, 24, 48 and 72 hours after intervention.

Method of measurement

Using non-compartmental model of Win-Nonlin Professional software version 3.2.A (Pharsight Corporation, USA)

Intervention groups

1

Description

Intervention group 1: ASAYER® 81 mg Enteric-coated Tablet , produced by Actoverco. is the test product. In each period, 12 of 24 subjects will be given single oral dose of this product. After 7-day wash-out period the intervention 2 will be given to these subjects.

Category

Treatment - Drugs

2

Description

Intervention group 2: Aspirin Bayer® 81mg tablet, produced by BAYER is the reference product. In each period, 12 of 24 subjects will be given single oral dose of this product. After 7-day wash-out period the intervention 1 will be given to these subjects.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hakim Farabi Clinic

Full name of responsible person

Ebrahim Siahpoosh

Street address

No. 57, Shemshad alley, in front of Sallor town.

City

Tehran

Province

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4635314588

Phone

+98 21 9253 5647

Email

partochem@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Actover Pharmaceutical Co.

Full name of responsible person

آقای دکتر رامین دانشمیر

Street address

No. 58, 8th St., Gisha

City

Tehran

Province

Tehran

Postal code

1446863914

Phone

+98 21 4162 7000

Email

info@actoverco.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Actover Pharmaceutical Co.

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

Noor Research & Development Institute

Full name of responsible person

Ali Aghaei

Position

Master

Latest degree

Master

Other areas of specialty/work

Pharmacy

Street address

Sharif innovation station, North Habibollah Street, Hosseini Square, Teymoury Street, Tarasht.

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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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Other areas of specialty/work
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Person responsible for updating data

Contact

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Other areas of specialty/work
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Email
partochem@gmail.com

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

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