

# 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/m<sup>2</sup>. 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)

##### Phone

+98 21 6600 7026

##### Email address

info@tavaninstitute.ir

##### 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/m<sup>2</sup>. 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<sub>max</sub>)

**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

Tehran

##### Postal code

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.

##### City

Tehran

##### Province

Tehran

##### Postal code

1459926609

**Phone**  
+98 21 6600 4027  
**Email**  
info@tavaninstitute.ir  
**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Tavan Institute  
**Full name of responsible person**  
Seyed Mohsen Foroutan  
**Position**  
Principal investigator  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Medical Pharmacy  
**Street address**  
Sharif innovation station, North Habibollah Street,  
Hosseini Square, Teymoury Street, Tarasht.  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1459926609  
**Phone**  
+98 21 6600 4027  
**Email**  
mforoutan@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tavan 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.  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1459926609  
**Phone**  
+98 21 6600 4027  
**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