Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Bioequivalence study of Naproxen 750mg Sustained Release tablets manufactured by Darman Yab Darou Pharmaceutical Company vs. Apo-Naproxen SR® tablets manufactured by Apotex Inc Company in healthy volunteers

Protocol summary

Study aim
Examining the bioequivalency of domestically produced Naproxen tablet formulations with brand one named Apo Naproxen

Design
A cross over, not blinded, randomized, bioequivalence clinical trial on 24 healthy volunteers.

Settings and conduct
Study place: Drug Applied Research Center affiliated to Tabriz University of Medical Science. The number of 24 volunteers in the age range of 18-55 years and the Body Mass Index range of 18-30, who are voluntarily selected through public notification. One tablet is taken fasting and blood is taken at 14 time points. A weeks later, the process is repeated for the brand medicine

Participants/Inclusion and exclusion criteria
Inclusion criteria: the weight range of 60-100 kg; being non-smoker; being healthy in terms of physical examination, ECG and the laboratory tests; Volunteers who have agreed to an informed consent form. Exclusion criteria: History of allergic or adverse reaction to Naproxen or any similar product; blood pressure less than 60/90 mm Hg or higher than 90/140 mm Hg; Individuals who have donated whole blood during the previous 2 months of the study or donated blood components within 2 weeks before taking the first dose of the drug

Intervention groups
Intervention group 1:Naproxen 750mg Sustained Release tablets manufactured by Darman Yab Darou Pharmaceutical Company is the test product. Intervention group 2: Apo-Naproxen SR® tablet manufactured by Apotex Pharmaceutical Company is the reference product. In each period, 12 of 24 subjects will be given single dose of this product and for up to 72 hours, 3 ml of blood will be collected from the volunteer at 14 time points each time. After the washout period, the volunteers are placed in the opposite group

Main outcome variables
Plasma concentration of the drug

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130313012810N125**
Registration date: **2026-08-13, 1405/05/22**
Registration timing: **prospective**

Last update: **2026-08-13, 1405/05/22**
Update count: **0**

Registration date
2026-08-13, 1405/05/22

Registrant information

Name
Hamed Hamishehkar

Name of organization / entity
Drug Applied Research Center, Tabriz University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 41 1336 3311

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2026-08-28, 1405/06/06

Expected recruitment end date

2026-08-30, 1405/06/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Bioequivalence study of Naproxen 750mg Sustained Release tablets manufactured by Darman Yab Darou Pharmaceutical Company vs. Apo-Naproxen SR® tablets manufactured by Apotex Inc Company in healthy volunteers

Public title

Naproxen tablet bioequivalence

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The weight range of participating candidates should be between 60-100 kg All candidates must be non-smokers Candidates should be healthy in terms of physical examination, ECG and the following laboratory tests: Hemoglobin, Hematocrit, Red and White Blood Count, MCV (Mean Body Volume), MCH (Mean Body Hemoglobin), Routine Urinalysis, Total Cholesterol, Triglyceride, Total Proteins, albumin, uric acid, total bilirubin, alkaline phosphatase, gamma glutamyl transpeptidase (γ-GT), aspartate aminotransferase (AST), alanine aminotransferase (ALT), urea, creatinine and fasting blood glucose. Volunteers who have agreed to an informed consent form All candidates should not consume caffeine-containing drinks and chocolate during two days before the prescription, and this restriction must be followed until the last blood draw

Exclusion criteria:

History of allergic or adverse reaction to Naproxen or any similar product Volunteers with blood pressure less than 60/90 mm Hg or higher than 90/140 mm Hg Individuals who have donated whole blood during the last 2 months from the study Individuals who have donated donated blood components within 2 weeks before taking the first dose of the drug

Age

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

Gender

Both

Phase

Bioequivalence

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

To randomly assign people in two groups, 24 cards with numbers 1 to 24 will be used in closed envelopes arranged irregularly. Each candidate will pick up an envelope after entering the study, and numbers 1-12 will be in group A and numbers 13-24 will be in group B. Group A will receive intervention 1, and group B will receive intervention 2, and after the first period, the interventions of both groups will change for the second period.

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 Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Daneshgah Street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5165665811

Approval date

2026-07-27, 1405/05/05

Ethics committee reference number

IR.TBZMED.REC.1405.279

Health conditions studied

1

Description of health condition studied

Bioequivalence study in healthy volunteers

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Plasma concentration of the drug

Timepoint

14 sampling time included pre-dose (time 0) and at the following hours post-dose: 1، 2، 3، 4، 5، 6، 7، 8، 10، 12، 24، 48، and 72 h

Method of measurement

Liquid Chromatography with tandem mass spectrometry (LC-MS-MS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: In this group, volunteers are given a single oral dose of Naproxen 750mg Sustained Release tablets manufactured by Darman Yab Darou Pharmaceutical Company. In each period, 12 of 24 subjects will be given a single oral dose of this product. After the washout period, the volunteers are placed in the Intervention group 2.

Category
Treatment - Drugs

2

Description
Intervention group 2: In this group, volunteers are given a single oral dose of Naproxen 750mg Sustained Release tablets manufactured by Apotex Company. In each period, 12 of 24 subjects will be given a single oral dose of this product. After the washout period, the volunteers are placed in the Intervention group 1.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Drug Applied Research Center, Tabriz University of Medical Sciences

Full name of responsible person
Hamed Hamishehkar

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Drug Applied Research Center, Tabriz University of Medical Sciences, Daneshgah Street, Tabriz

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hamishehkar.hamed@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Darman Yab Darou Pharmaceutical Company

Full name of responsible person
پریسا منصوری

Street address
No. 36, corner of Azadegan, 20th street (Shahid Abtahi), Kurdistan highway

City
Tehran

Province
Tehran

Postal code
1437634561

Phone
+98 21 87174

Email
drugsafety@darmanyab.com

Grant name

Grant code / Reference number

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

Title of funding source
Darman Yab Darou 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
Tabriz University of Medical Sciences

Full name of responsible person
Hamed Hamishehkar

Position
professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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Person responsible for scientific inquiries

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Position
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Person responsible for updating data

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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
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