

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Bioequivalence Study of Injectable Extended-Release Naltrexone (380 mg) of Nano Daru pharma Co. (Exopio®) and Vivitrol® (as a reference) in Iranian Healthy volunteers

Protocol summary

Study aim

Bioequivalence Study of Injectable Extended-Release Naltrexone (380 mg) of Nano Daru pharma Co. (Exopio®) and Vivitrol® (as a reference) in Iranian Healthy volunteers

Design

parallel study

Settings and conduct

48 healthy subjects are enrolled. The study is a single-blind. In this study, under supervision of study investigators, a single dose of Injectable Extended-Release Naltrexone (380 mg), test or reference is administered intramuscularly to healthy subjects. For the measurement of pharmacokinetic parameters, 5 ml blood samples are taken before (0 min) and at 1, 2, 4, 8, 12, 24, 32, 38, 48 and 58 hours and 3, 5, 7, 10, 14, 18, 24, 30 days after administration.

Participants/Inclusion and exclusion criteria

inclusion criteria: healthy volunteers exclusion criteria: Significant history or presence of gastrointestinal, kidney disease or any other conditions known to interfere with the absorption, distribution, metabolism or excretion of common medications. Any clinically significant illness during the 4 weeks prior to day of this study.

Intervention groups

The administration of two products is carried out by a randomized and parallel study design. Subjects are randomly divided into two equal groups and assigned to one of the two groups of drug administration. Exopio®, as a test drug, is administered in one group and Vivitrol®, as a reference drug, is administered in another group.

Main outcome variables

drug concentration in blood plasma

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130603013572N4**

Registration date: **2020-08-10, 1399/05/20**

Registration timing: **prospective**

Last update: **2020-08-10, 1399/05/20**

Update count: **0**

Registration date

2020-08-10, 1399/05/20

Registrant information

Name

Mohammadreza Rouini

Name of organization / entity

Tehran University of Medical Sciences, Faculty of Pharmacy

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2022-03-16, 1400/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Bioequivalence Study of Injectable Extended-Release Naltrexone (380 mg) of Nano Daru pharma Co. (Exopio®) and Vivitrol® (as a reference) in Iranian Healthy volunteers

Public title

Bioequivalence Study of Injectable Extended-Release Naltrexone (380 mg) of Nano Daru pharma Co. (Exopio®) and Vivitrol® (as a reference) in Iranian Healthy volunteers

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

healthy male and female volunteers Age: between 18 and 55 years old BMI: between 18.5 and 30 kg/m2

Exclusion criteria:

History of hypersensitivity to the study drug or related products. Significant history or presence of gastrointestinal, kidney disease or any other conditions known to interfere with the absorption, distribution, metabolism or excretion of common medications. Significant history of asthma, chronic bronchitis or other broncho spastic condition. Significant history or presence of glaucoma, cardiovascular or hematological disease. Any clinically significant illness during the 4 weeks prior to day of this study. Maintenance therapy with any drug, or history of drug dependency, alcohol abuse, or serious neurological or psychological disease. Participation in a clinical trial with an investigation drug within 30 days preceding day 1 of this study. Use of enzyme- modifying drugs within 30 days prior to day 1 of this study. Use of any systemic medication (including OTC preparations) within 14 days prior to day 1 of this study. HIV and Hepatitis B and anti HCV antibody positive subjects. Smoking History of difficulty in donating blood Donation of blood within 90 days before first dosing. History of vaccination within one month before first dosing.

Age

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

Gender

Both

Phase

Bioequivalence

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization administrating of test or reference product for each subject is determined according to the randomization schedule. The randomization schedule is prepared according to volunteer's allocated number. Each subject is identified by a number from 1 to 48

according to their entrance to volunteers' list in screening day. Randomly, Subjects with odd numbers receive the test drug and the subjects with even number receive the reference drug.

Blinding (investigator's opinion)

Single blinded

Blinding description

Volunteers are blind in this study. The volunteers, according to the predetermined random table that is available to the researcher, are in one of the groups receiving the test or reference drug. Volunteers are aware that they are receiving the test drug (Iranian) and the reference drug (approved drug), but they do not know in which study period they will receive the test and reference drug.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Vice-chancellor in research affairs- Tehran university of medical sciences

Street address

Keshavarz Blvd., Tehran, Iran

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Province

Tehran

Postal code

1416753955

Approval date

2020-05-05, 1399/02/16

Ethics committee reference number

IR.TUMS.VCR.REC.1399.341

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

Bioequivalence Study of Injectable Extended-Release Naltrexone (380 mg) of Nano Daru pharma Co. (Exopio®) and Vivitrol® (as a reference) in Iranian Healthy volunteers

ICD-10 code**ICD-10 code description****Primary outcomes**

1

Description

determination of drug concentration in blood plasma

Timepoint

(0 min) and at 1, 2, 4, 8, 12, 24, 32, 38, 48 and 58 hours and 3, 5, 7, 10, 14, 18, 24, 30 days after administration

Method of measurement

High performance liquid chromatography

Secondary outcomes

1

Description

time to peak plasma concentration

Timepoint

(0 min) and at 1, 2, 4, 8, 12, 24, 32, 38, 48 and 58 hours and 3, 5, 7, 10, 14, 18, 24, 30 days after administration

Method of measurement

observational

2

Description

maximum plasma concentration

Timepoint

(0 min) and at 1, 2, 4, 8, 12, 24, 32, 38, 48 and 58 hours and 3, 5, 7, 10, 14, 18, 24, 30 days after administration

Method of measurement

observational

3

Description

Area under the plasma concentration-time curves

Timepoint

(0 min) and at 1, 2, 4, 8, 12, 24, 32, 38, 48 and 58 hours and 3, 5, 7, 10, 14, 18, 24, 30 days after administration

Method of measurement

linear trapezoidal method

Intervention groups

1

Description

Intervention group: Single dose administration of Injectable Extended-Release Naltrexone (Exopio®) (380 mg) manufactured by Nano Daru pharma Co. in 24 healthy volunteers

Category

Other

2

Description

Control group: Single dose administration of Injectable Extended-Release Naltrexone (Vivitrol®) (380 mg) manufactured by Alkermes pharma Co. in 24 healthy volunteers

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran university of medical sciences

Full name of responsible person

Mohammadreza Rouini

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16th Azar St., Enghelab Sq., Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Nano Daru pharmaceutical Co.

Full name of responsible person

Dr. Navid Godarzi

Street address

Northern Tak Ave., Attar St., Vanak Sq., Tehran, Iran

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Tehran

Postal code

1994754953

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Email

goodarzi@nanodaru.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Nano Daru 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

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammadreza Rouini

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Pharmaceutics and Biopharmaceutics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

No - There is not a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to
make this available
Title and more details about the data/document

Only protocol and methods of study are shareable

When the data will become available and for how long

Starting access 6 months after publication of data

To whom data/document is available

Pharmaceutical and medical sciences researchers

Under which criteria data/document could be used

Using is not authorized

From where data/document is obtainable

contact with E-mail of the main researcher

What processes are involved for a request to access data/document
Personal and academic details and the aim of data
request.
Comments