Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

A study to compare the relative bioavailability of Toliddaru and Astellas formulations of solifenacin 10 mg tablets in 24 healthy adult volunteers under fasting conditions.

Protocol summary

Study aim
The study aims to evaluate the bioequivalence of solifenacin 10 mg tablets produced by two different pharmaceutical companies under fasting conditions

Design
This randomized, single-dose, two-way, crossover study is conducted to compare the pharmacokinetics of Solifenacin and Vesicare® tablets in 24 healthy adult volunteers. Volunteers will be sorted and receive a number from 1 to 24. In the first phase of the study, 12 volunteers will receive Solifenacin manufactured by Toliddaru and the remaining 12 volunteers will receive Vesicare® produced by Astellas company. The administered drugs will be replaced to another group in the second phase of the study.

Settings and conduct
The dose injection and subsequent sample collection will be performed in S. Motahhari hospital (Gonbade Kavous, Iran).

Participants/Inclusion and exclusion criteria
Inclusion criteria: aged 18-55 years; subject available for the entire study period; willingness to adhere to protocol requirements as evidenced by written informed consent; good health at screening. Exclusion criteria: History of use of any drug; hypersensitivity or intolerance; significant history or current evidence of chronic disease; receipt of any drug as part of a research study within 30 days prior to the present study.

Intervention groups
First intervention group: A single 10 mg oral dose of solifenacin (1 tablet) manufactured by Toliddaru company to 12 subjects. Second intervention group: A single 10 mg oral dose of Vesicare (1 tablet) manufactured by Astellas company to 12 subjects. Since in this study, the volunteers will receive both test and reference drugs, each volunteer will act as his own control.

Main outcome variables
Drug plasma concentration; Area under the plasma concentration-time curve

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130626013776N45**
Registration date: **2021-06-05, 1400/03/15**
Registration timing: **prospective**

Last update: **2021-06-05, 1400/03/15**
Update count: **0**

Registration date
2021-06-05, 1400/03/15

Registrant information

Name
Hossein Amini

Name of organization / entity
Golestan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-23, 1400/05/01

Expected recruitment end date
2022-05-22, 1401/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A study to compare the relative bioavailability of Toliddaru and Astellas formulations of solifenacin 10 mg tablets in 24 healthy adult volunteers under fasting conditions.

Public title

Bioequivalence study of solifenacin 10 mg tablets

Purpose

Basic scienece

Inclusion/Exclusion criteria

Inclusion criteria:

18-55 years of age The subject is able and willing to provide signed informed consent The subject is available for the entire study period Willing to adhere to protocol requirements as evidenced by written informed consent The subject has a stable residence and telephone Good health as determined by lack of clinically significant abnormalities in health assessments performed at screening

Exclusion criteria:

History of allergy or sensitivity to solifenacin History of any drug hypersensitivity or intolerance which, in the opinion of the investigator, would compromise the safety of the subject of the study Significant history or current evidence of chronic infectious disease, system disorder or organ dysfunction. Presence of gastrointestinal disease or history of malabsorption within the last year. History of a medical disorders occurring within the last year that required hospitalization or medication Use of pharmacologic agents known to significantly induce or inhibit drug-metabolizing enzymes within 30 days prior to dosing. Receipt of any drug as part of a research study within 30 days prior to the present study Donation or significant loss of whole blood (480 ml or more) within 30 days prior to the present study

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**

More than 1 sample in each individual

Number of samples in each individual: **2**

In a crossover design, each person is its own control and receives two different interventions

Randomization (investigator's opinion)

Randomized

Randomization description

A pot sampling method will be used in this study. 12 papers are labeled "Reference Product" and 12 papers are written as "Test Product". The papers are then placed in sealed envelopes, and participants randomly select a paper and will be placed in the Reference or Test groups.

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 Golestan University of Medical Sciences

Street address

Gorgan, Shast cola road, Falsafi Building

City

Gorgan

Province

Golestan

Postal code

4916817693

Approval date

2021-05-23, 1400/03/02

Ethics committee reference number

IR.GOUMS.REC.1400.050

Health conditions studied

1

Description of health condition studied

.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Drug plasma concentration

Timepoint

At time zero and 1, 2, 3, 4, 5, 6, 7, 8, 10, 12, 24, 48 and 72 hours after dosing

Method of measurement

Blood sampling and measurement of drug concentrations by high-performance liquid chromatography

2

Description

Area under plasma concentration-time curve

Timepoint
At time zero and 1, 2, 3, 4, 5, 6, 7, 8, 10, 12, 24, 48 and 72 hours after dosing
Method of measurement
Blood sampling and measurement of drug concentrations by high-performance liquid chromatography

Secondary outcomes

1

Description
Plasma half-life
Timepoint
From the terminal 66 hours of plasma concentration-time profile
Method of measurement
Blood sampling and drug analysis by high-performance liquid chromatography method

Intervention groups

1

Description
Intervention group: Oral administration of a single 10 mg dose of solifenacin (1 tablet) manufactured by Toliddaru to healthy volunteers under fasting condition in the morning of the experiment day.
Category
Treatment - Drugs

2

Description
Intervention group: Oral administration of a single 10 mg dose of Vesicare (1 tablet) manufactured by Astellas to healthy volunteers under fasting condition in the morning of the experiment days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dialysis Center, S. Motahhari Hospital
Full name of responsible person
Yahya Naserifard
Street address
Taleghani Street
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haminhplc@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Toliddaru Pharmaceuticals
Full name of responsible person
Dr. Monirosadat Ahmadi
Street address
Saveh highway, S. Yadegar street
City
Tehran
Province
Tehran
Postal code
1371616314
Phone
+98 21 6662 0175
Email
mmahmadi17@yahoo.com
Web page address
http://www.toliddaru.ir/
Grant name
Bioequivalence Study of Solifenacin
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Toliddaru Pharmaceuticals
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
Gorgan University of Medical Sciences
Full name of responsible person
Hossein Amini
Position
Associate professor
Latest degree
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Other areas of specialty/work
Medical Pharmacy
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Data are confidential and need permission from the company
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