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A study to assess the amount of sildenafil that reaches the blood circulation after administration of an oral film dissolvable in the mouth for treating erectile dysfunction in comparison to the marketed tablet Viagra®, both taken by healthy men under fed conditions

Submission date
19/12/2022

Recruitment status
No longer recruiting

Registration date
10/01/2023

Overall study status
Completed

Last Edited
25/11/2025

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
A new oral film containing sildenafil citrate, the active ingredient of Viagra used to treat erectile dysfunction, has been recently developed. It dissolves very rapidly in the oral mouth, with no need for drinking or chewing, thus providing an alternative to the marketed solid oral forms (tablets) in the treatment of erectile dysfunction. This study is designed to investigate the amount of the drug that reaches the blood flow after administration of the new sildenafil oral film with and without water in comparison to the marketed tablet Viagra®.

Who can participate?
Healthy men aged 18-55 years can participate. They must comprehend the full nature and purpose of the study, including possible risks and side effects, and co-operate with the investigator to comply with the requirements of the entire study.

What does the study involve?
The study will be conducted at CROSS Research S.A. Phase I Unit Clinical Center, in Arzo, Switzerland. Study participants will receive a single oral dose of Sildenafil IBSA 100 mg oral film without water, a single oral dose of Sildenafil IBSA 100 mg oral film with water and a single oral dose of Viagra® 100 mg film-coated tablet in 3 study periods, under fed conditions, with a wash-out interval of at least 5 days between the 3 administrations. Participants will have blood samples taken and vital parameters recorded at regular intervals.

What are the possible benefits and risks of participating?
Participating in this study will not bring any direct benefit to participants, with the exception of the medical tests that will be performed during it. On the basis of sildenafil safety profile, no

particular risks are expected. However, as with all products, the appearance of allergic reactions or side effects that are known or not yet known cannot be ruled out.

Where is the study run from?
The study will be conducted at the CROSS Research S.A. Phase I Unit Clinical Center, in Arzo, Switzerland.

When is the study starting and how long is it expected to run for?
July 2020 to January 2021

Who is funding the study?
IBSA Institut Biochimique S.A. (Switzerland)

Who is the main contact?
Dr Milko Radicioni, clinic@croalliance.com

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
20CH-SDF10

Study information

Scientific Title
Comparative bioavailability study of Sildenafil 100 mg oral film vs. Viagra® 100 mg film-coated tablet administered to healthy men under fed conditions

Study objectives
To compare the bioavailability of sildenafil and its metabolite N-desmethyl-sildenafil after single dose administration of Sildenafil IBSA 100 mg oral film and Viagra® 100 mg film-coated tablet to healthy male volunteers under fed conditions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/07/2020, Canton Ticino Ethics committee (c/o Ufficio di sanità, Via Orico 5, 6501 Bellinzona, Switzerland; +41(0)91.814.30.57; beatrice.giberti-gai@ti.ch), ref: 2020-01698 / CE-3698

Primary study design
Interventional

Study design
Single-center single-dose randomized open-label three-way cross-over fed conditions bioavailability study

Study type(s)
Other

Health condition(s) or problem(s) studied
Erectile dysfunction

Interventions
A single dose of the investigational medicinal product (Sildenafil IBSA 100 mg oral film) without water, a single dose of the investigational medicinal product with water and a single dose of Viagra® 100 mg film-coated tablet will be administered to the study subjects in three study periods, according to a 3-way cross-over randomised design, under fed conditions, with a wash-out interval of at least 5 days between the three administrations.

The investigational medicinal products will be orally administered on day 1 of each study period at 08:00±1 h as follows:
- one Sildenafil IBSA 100 mg oral film will be administered to the subjects without water. For the administration, the Investigator or his deputy will take the film out of the sachet and place it directly on the subject's tongue. The Investigator will wear gloves during the administration procedure. The film will dissolve rapidly. Subjects will let the oral film completely dissolve in their mouth. The film must NOT be swallowed whole and must NOT be chewed or broken. The subject will be allowed to swallow saliva as the film dissolves in the mouth. When the subject indicates complete disintegration of the oral film, a visual inspection will be performed. In details, once the subject feels that the film has completely dissolved, he will inform the Investigator who will inspect the subject’s mouth and verify the complete dissolution in the mouth. If the subject does not inform the investigator within one min of the administration, his mouth will be checked by the Investigator. Film dissolution times will be collected in the specific source documents and subjects’ CRFs.
- one Sildenafil IBSA 100 mg oral film will be administered to the subjects with water. For the administration, the procedure previously described for the administration without water will be followed. After complete film dissolution, the subjects will drink 240 mL of still mineral water.
- one Viagra® 100 mg film-coated tablet will be administered to the subjects together with 240 mL of still mineral water. The tablet must be swallowed whole and must not be chewed or broken.
The volunteers will receive the three investigational treatments in the three study periods under fed conditions, i.e. 30 min after starting a high-fat and high-caloric breakfast.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
Sildenafil

Primary outcome(s)
Rate (Cmax) and extent (AUC0-t and AUC0-inf, if feasible) of sildenafil absorption in plasma measured from plasma samples taken at pre-dose (0) and 6, 15, 30, 45 min and 1, 1.25, 1.5, 2, 2.5, 3, 4, 6, 8, 12, 16 and 24 h post-dose.

Key secondary outcome(s)
1. Time to peak (tmax), relative bioavailability (Frel) and, if feasible, elimination half-life (t1/2) and terminal elimination rate constant (λz) of plasma sildenafil measured from plasma samples taken at pre-dose (0) and 6, 15, 30, 45 min and 1, 1.25, 1.5, 2, 2.5, 3, 4, 6, 8, 12, 16 and 24 h post-dose
2. Rate (Cmax) and extent (AUC0-t and AUC0-inf if feasible) of absorption, time to peak (tmax), relative bioavailability (Frel) and, if feasible, elimination half-life (t1/2) and terminal elimination rate constant (λz) of plasma N-desmethyl-sildenafil measured from plasma samples taken at pre-dose (0) and 6, 15, 30, 45 min and 1, 1.25, 1.5, 2, 2.5, 3, 4, 6, 8, 12, 16 and 24 h post-dose
3. All adverse events occurring or worsening after the informed consent signature before (PTAEs) and after (TEAEs) the first dose of investigational medicinal product, vital signs (blood pressure and heart rate, measured at screening visit, in each study period at pre-dose (0), 1.5 and 24 h post-dose, at early termination visit [ETV] if applicable), body weight (measured at screening and final visit/ETV as applicable), physical examinations (performed at screening and final visit/ETV as applicable), clinical laboratory parameters (haematology, blood chemistry and urine analysis performed at screening and final visit/ETV as applicable; virology performed at screening visit; urine drug test performed at screening and at the entrance of each study period), ECG (performed at screening, in each study period at 24 h post-dose, at ETV, if applicable).

Completion date
28/01/2021

Eligibility

Key inclusion criteria
1. Informed consent: signed written informed consent before inclusion in the study
2. Sex and Age: males, 18-55 years old inclusive
3. Body Mass Index: 18.5-30 kg/m² inclusive
4. Vital signs: systolic blood pressure 100-139 mmHg, diastolic blood pressure 50-89 mmHg, heart rate 50-90 bpm, measured after 5 min at rest in the sitting position
5. Full comprehension: ability to comprehend the full nature and purpose of the study, including possible risks and side effects; ability to co-operate with the Investigator and to comply with the requirements of the entire study.

Participant type(s)

Healthy volunteer

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
Male

Total final enrolment
35

Key exclusion criteria
1. Electrocardiogram (12-lead ECG in supine position): clinically significant abnormalities; out of range intervals (PR <110 msec, PR >200 msec, QRS <60 msec, QRS >110 msec and QTc > 440 msec)
2. Physical findings: clinically significant abnormal physical findings which could interfere with the objectives of the study; presence or history (within 28 days) of any tongue piercings; presence of any partials, braces or dentures
3. Laboratory analyses: clinically significant abnormal laboratory values indicative of physical illness
4. Allergy: ascertained or presumptive hypersensitivity to the active principle and/or formulations' ingredients; history of anaphylaxis to drugs or allergic reactions in general, which the Investigator considers may affect the outcome of the study
5. Diseases: significant history of renal, hepatic, gastrointestinal, cardiovascular, respiratory, skin, haematological, endocrine or neurological diseases that may interfere with the aim of the study; history of vision or hearing problems related to drugs of the PDE5 inhibitor pharmacological class; history of priapism; anatomical deformation of the penis (such as angulation, cavernosal fibrosis or Peyronie’s disease); history of ophthalmologic diseases like non-arteritic anterior ischemic optic neuropathy or retinitis pigmentosa
6. Medications: medications, including over the counter (OTC) medications and herbal remedies for 2 weeks before the start of the study. Organic nitrates will not be allowed for 28 days before screening
7. Investigative drug studies: participation in the evaluation of any investigational product for 3 months before this study. The 3-month interval is calculated as the time between the first calendar day of the month that follows the last visit of the previous study and the first day of the present study
8. Blood donation: blood donations for 3 months before this study
9. Drug, alcohol, caffeine, tobacco: history of drug, alcohol [>2 drinks/day, defined according to the USDA Dietary Guidelines 2015-2020], caffeine (>5 cups coffee/tea/day) or tobacco abuse (10 cigarettes/day)
10. Drug test: positive result at the drug test at screening or day-1
11. Alcohol test: positive alcohol breath test at day -1

12. Diet: abnormal diets (<1600 or >3500 kcal/day) or substantial changes in eating habits in the 4 weeks before this study; vegetarians.

Date of first enrolment
01/12/2020

Date of final enrolment
09/12/2020

Locations

Countries of recruitment
Switzerland

Study participating centre
CROSS Research S.A.
Via F.A. Giorgioli 14
Arzo
Switzerland
6864

Sponsor information

Organisation
IBSA Institut Biochimique (Switzerland)

ROR
https://ror.org/051tj3a26

Funder(s)

Funder type
Not defined

Funder Name
IBSA Institut Biochimique S.A.

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository: the IBSA Institut Biochimique S.A. repository.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		23/11/2025	25/11/2025	Yes	No
Basic results		27/03/2023	27/03/2023	No	No
Protocol file	version 3.0	10/05/2021	22/12/2022	No	No