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Pharmacokinetics of a novel sildenafil orodispersible film administered by the supralingual and the sublingual route to healthy men

Submission date
17/11/2020

Recruitment status
No longer recruiting

Registration date
25/11/2020

Overall study status
Completed

Last Edited
25/11/2020

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] 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 in Viagra, which is used to treat erectile dysfunction (ED), 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 ED. This study aims to investigate whether the oral film is absorbed in the same way following two different administration methods: the approved supralingual (dissolved above the tongue) administration and the alternative sublingual (dissolved underneath the tongue) administration.

Who can participate?
Healthy men aged 18-45 years

What does the study involve?
The study has two periods, and participants will be randomly allocated into one section and then will rotate through each period such that every participant completes all periods of the trial but the order will vary depending on the period they are initially allocated to:
Period A: Single dose of the study drug dissolved under the tongue, under fasting conditions
Period B: Single dose of the study drug dissolved above the tongue, under fasting conditions

There will be a break of at least 5 days between the periods.

The blood level of sildenafil is measured before taking the study drug and again after 6, 15, 30, 45 min and 1, 1.25, 1.5, 2, 2.5, 3, 4, 6, 8, 12 h.

What are the possible benefits and risks of participating?
There are no known benefits or risks to participants taking part in this study.

Where is the study run from?
CROSS Research S.A., Phase I Unit (Switzerland)

When is the study starting and how long is it expected to run for?
From November 2017 to December 2017

Who is funding the study?
IBSA Institut Biochimique SA (Switzerland)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
Study CRO-PK-17-325, Sponsor code 17CH-SDF06

Study information

Scientific Title
Pilot bioavailability study of sildenafil 50 mg orodispersible film administered by the supralingual and the sublingual route to healthy men

Study objectives
To compare the bioavailability of sildenafil and its metabolite N-desmethyl-sildenafil after single dose of sildenafil IBSA 50 mg orodispersible film (ODF), administered by the supralingual and the sublingual route.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/09/2017, Cantonal Ethics Committee of the Canton of Ticino (Cantonal Ethics Committee, c/o Health Office, Via Orico 5, 6501 Bellinzona, Switzerland; +41 91 814 30 57; dss-ce@ti.ch), ref: CE3268, BASEC ref: 2017-01622

Study design
Single dose, open, randomised, 2-way cross-over pilot bioavailability study

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
The study has two periods, and participants will be randomly allocated into one section and then will rotate through each period such that every participant completes all periods of the trial but the order will vary depending on the period they are initially allocated to:
Period A: Single dose of 50 mg sildenafil orodispersible film (ODF) (IBSA Institut Biochimique S. A., Switzerland) by the sublingual administration routes, under fasting conditions
Period B: Single dose of 50 mg sildenafil orodispersible film (ODF) (IBSA Institut Biochimique S. A., Switzerland) by the supralingual administration routes, under fasting conditions

There will be a break of at least 5 days between the periods.

The plasma level of sildenafil is measured before taking the study drug (baseline/0 min) and again after 6, 15, 30, 45 min and 1, 1.25, 1.5, 2, 2.5, 3, 4, 6, 8, 12 h.

Intervention Type
Drug

Phase
Phase I

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

Primary outcome(s)
1. Plasma sildenafil maximum serum concentration (Cmax) and area under the plasma drug concentration-time curve (AUC0-t) are measured from plasma samples taken at baseline, and 6, 15, 30, and 45 min, and 1, 1.25, 1.5, 2, 2.5, 3, 4, 6, 8, and 12 h

Key secondary outcome(s))
1. Plasma sildenafil time take to reach Cmax (tmax), relative bioavailability (Frel), and, if feasible, area under the plasma concentration-time curve from time zero to infinity (AUC0-∞), elimination

half-life (t1/2), and terminal disposition rate constant/terminal rate constant (λz) are measured from plasma samples taken at baseline, and 6, 15, 30, and 45 min, and 1, 1.25, 1.5, 2, 2.5, 3, 4, 6, 8, and 12 h
2. Plasma N-desmethyl-sildenafil time take to reach Cmax (tmax), area under the plasma drug concentration-time curve (AUC0-t), relative bioavailability (Frel), and, if feasible, area under the plasma concentration-time curve from time zero to infinity (AUC0-∞), elimination half-life (t1/2), and terminal disposition rate constant/terminal rate constant (λz) are measured from plasma samples taken at baseline, and 6, 15, 30, and 45 min, and 1, 1.25, 1.5, 2, 2.5, 3, 4, 6, 8, and 12 h

Completion date
13/12/2017

Eligibility

Key inclusion criteria
1. Signed written informed consent before inclusion in the study
2. Male participants aged between 18-45 years inclusive
3. Body Mass Index (BMI) between 18.5-30 kg/m² inclusive
4. Systolic blood pressure between 100-139 mmHg, diastolic blood pressure between 50-89 mmHg, heart rate between 50-90 bpm (all measured after 5 min at rest in the sitting position)
5. Ability to comprehend the full nature and purpose of the study, including possible risks and side effects, to co-operate with the investigator, and to comply with the requirements of the entire study

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
45 years

Sex
Male

Total final enrolment
12

Key exclusion criteria
1. Clinically significant abnormalities on electrocardiogram (12-lead ECG in supine position)
2. Clinically significant abnormal physical findings which could interfere with the objectives of the study
3. Clinically significant abnormal laboratory values indicative of physical illness

4. Ascertained or presumptive hypersensitivity to the active principle and/or formulations' ingredients, or history of anaphylaxis to drugs or allergic reactions in general, which the investigator considered could affect the outcome of the study
5. Significant history of renal, hepatic, gastrointestinal, cardiovascular, respiratory, skin, haematological, endocrine or neurological diseases that could 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); or history of ophthalmologic diseases like non-arteritic anterior ischemic optic neuropathy or retinitis pigmentosa

Date of first enrolment
27/11/2017

Date of final enrolment
13/12/2017

Locations

Countries of recruitment
Switzerland

Study participating centre
CROSS Research S.A., Phase I Unit
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Sponsor information

Organisation
IBSA Institut Biochimique (Switzerland)

ROR
https://ror.org/051tj3a26

Funder(s)

Funder type
Industry

Funder Name

IBSA Institut Biochimique S.A.

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	16/06/2018		Yes	No