

A study comparing a new lidocaine plaster (IBSA Lidocaine 5% medicated plaster) to the marketed Versatis® plaster in healthy volunteers – looking at how well the new plaster delivers the medicine into the body (bioequivalence), how well it sticks to the skin (adhesion), and how the skin reacts (tolerability)

Submission date 26/08/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/09/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 28/08/2025	Condition category Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

A new medicated plaster containing 5% lidocaine has been developed by IBSA Institut Biochimique to provide local pain relief. The product has already been approved in the USA and IBSA is currently planning to register it in EU.

This study was carried out to compare how well this new plaster delivers the medicine into the body, compared to the existing product Versatis® 700 mg medicated plaster. The goal was to see if both plasters result in similar levels of the medicine in the body when used by healthy men and women.

The study also looked at how well the plasters stick to the skin, how safe and well tolerated they are, and evaluated other related aspects.

Who can participate?

Healthy men and women aged 30-65 years can participate. They must comprehend the full nature and purpose of the study, including possible risks and side effects, and cooperate with the investigator to comply with the requirements of the entire study.

What does the study involve?

The study was conducted at the CROSS Research S.A. Phase I Unit Clinical Centre, in Arzo, Switzerland. Each participant received one dose of treatment by applying three plasters (a total of 2100 mg) to the back. The study was carried out in two separate periods: in one period, the new plaster was used, and in the other, the approved reference plaster. The order was chosen randomly for each participant. On the third day of each study period, one additional patch (700

mg) was also applied.

There was a break of at least 5 days between the two periods to allow the medicine from the first treatment to leave the body completely.

All plasters were applied to the back at around 8:00 in the morning (within a 1-hour window) and were kept on the skin for 12 hours before being removed.

Participants had blood samples taken and vital parameters recorded at regular intervals. At regular timepoints plasters were evaluated to check how well they stuck to the skin, how safe and well tolerated they were, and to evaluate other related aspects. Photographs of the plasters and of the back of the participants were taken as well.

What are the possible benefits and risks of participating?

Participating in this study did not bring any direct benefit to participants, except for the medical tests that were performed during it. The product had already been on the market, and data from other clinical studies had not shown any serious problems. For this reason, no major risks were expected for the people taking part in this study.

Where is the study run from?

The study was conducted at the CROSS Research S.A. Phase I Unit Clinical Centre, in Arzo (Switzerland)

When is the study starting and how long is it expected to run for?

October 2024 to May 2025

Who is funding the study?

IBSA Institut Biochimique S.A. (Switzerland)

Who is the main contact?

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

Study CRO-PK-24-369, Sponsor code 24CH-Lip02

Study information

Scientific Title

Bioequivalence, adhesion and tolerability study of a new IBSA Lidocaine 5% medicated plaster versus the marketed Versatis® 700 mg medicated plaster in healthy volunteers

Study objectives

Primary objective:

To evaluate the bioequivalence of the new IBSA Lidocaine 5% medicated plaster (test) versus the marketed Versatis® 700 mg medicated plaster (reference), by evaluating rate and extent of absorption of lidocaine after single application of the two products in healthy men and women.

Secondary objectives:

1. To evaluate the plasma pharmacokinetic profile and parameters of lidocaine after single application of test and reference
2. To evaluate the adhesion of test and reference
3. To collect safety and tolerability data of test and reference

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 10/12/2024, Canton Ticino Ethics Committee (c/o Ufficio di Sanità, Via Orico 5, Bellinzona, 6501, Switzerland; +41 (0)918143057; michaela.gutacker@ti.ch), ref: 2024-02349, 4726

Study design

Single-centre single-dose open-label randomized two-way cross-over bioequivalence, adhesion and tolerability study

Primary study design

Interventional

Secondary study design

Randomised cross over trial

Study setting(s)

Pharmaceutical testing facility

Study type(s)

Other

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Healthy volunteers

Interventions

Test product: IBSA Lidocaine 5% medicated plaster, IBSA Institut Biochimique S.A., Switzerland
Reference product: Versatis® (lidocaine) 700 mg medicated plaster, Grünenthal, Österreich

For each participant, a single dose of 2100 mg (three medicated plasters) of test and reference was applied in two study periods, according to a two-way cross-over randomised design. Furthermore, on Day 3 of each study period, an additional medicated plaster (700 mg) was applied. A wash-out interval of at least 5 days elapsed between the last application of period 1 and the first of period 2. All investigational products were applied on the back of the study participant, at 08:00 ± 1 h, and kept in place for 12 h before removal.

The Investigator assessed the plaster adhesion on Day 3 immediately after the application (0 h), at 2, 4 and 8 h post-application, and immediately before the plaster removal (12 h post-application). For each assessment, both a 6-point numerical scale and estimated percentage of adhered plaster surface area were used. In addition, digital photographs were taken immediately after each assessment.

The Investigator or deputy also assessed the qualitative aspects of the plaster on Day 3 at plaster application (0 h), at 2, 4 and 8 h post-application, and at the plaster removal (12 h post-application). In addition, digital photographs were taken immediately after each assessment.

The safety of the products was evaluated through the collection of treatment-emergent adverse events, vital signs (blood pressure, heart rate), physical examinations including body weight, ECG and clinical laboratory parameters.

Local tolerability was evaluated on Day 1 of each study period, before plaster application and after plaster removal. Skin reactions were scored according to a 4-grade scale.

Intervention Type

Drug

Pharmaceutical study type(s)

Bioequivalence

Phase

Phase I

Drug/device/biological/vaccine name(s)

IBSA Lidocaine 5% medicated plaster, Versatis® (lidocaine) 700 mg medicated plaster

Primary outcome measure

C_{max}, AUC_{0-t} and, if feasible, AUC_{0-∞} of plasma lidocaine after single application of test and reference. These parameters were evaluated analysing venous blood samples collected from participants' forearm veins at the following times:

On Day 1 of each study period at pre-application (0) and 1, 1.5, 2, 3, 4, 5, 6, 9, 12, 15 h post-application

On Day 2 of each study period at 18, 21, 24, 30 and 36 h post-application

Secondary outcome measures

1. Plasma lidocaine concentration profile and pharmacokinetic parameters (t_{max} and, if feasible, %AUC_{extra}, t_{1/2} and λ_Z) of plasma lidocaine after single application of test and reference.

These parameters were evaluated analysing venous blood samples collected from participants' forearm veins at the following times:

On Day 1 of each study period at pre-application (0) and 1, 1.5, 2, 3, 4, 5, 6, 9, 12, 15 h post-application

On Day 2 of each study period at 18, 21, 24, 30 and 36 h post-application

2. Adhesion scores and estimated percentages of adhered plaster area for test and reference. Plaster adhesion was evaluated on Day 3 of each study period immediately after the application (0 h), at 2, 4 and 8 h post-application, and immediately before the plaster removal (12 h post-application). The assessment was visually performed using a specific 6-point scale. In addition, at each time point, the actual percentage adhesion value (%) was estimated.

3. Treatment-emergent adverse events, vital signs (blood pressure, heart rate), ECG, local tolerability, physical examination, body weight, clinical laboratory parameters. Vital signs were evaluated through a sphygmomanometer approximately at each visit. ECG, visual physical examination, and body weight (through an electronic weighing scale) were evaluated at screening and final visits. Local tolerability was evaluated in all subjects on Day 1, before plasters' application and after plasters' removal. Skin reactions were scored according to a specific four-grade scale.

Other outcomes measures (qualitative aspects):

1. Presence of residual adhesive paste on the release liner at the removal from each plaster
2. Presence of residual adhesive paste on the skin of the application site after plaster removal
3. Presence of a cold-flow, i.e., the formation of a dark ring around the plaster during the application time

4. Movement, displacement or wrinkling of the plaster during the application time
All qualitative aspects were visually evaluated on Day 3 of each study period at the application time (0 h) and at 2, 4, 8 and 12 h post-application.

Overall study start date

16/10/2024

Completion date

05/05/2025

Eligibility

Key inclusion criteria

1. Informed consent: signed written informed consent before inclusion in the study
2. Sex and age: men and women, 30-65 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 50-99 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
6. Contraception and fertility (women only): women of child-bearing potential must be using at least one of the following reliable methods of contraception:
 - 6.1. Hormonal oral, implantable, transdermal, or injectable contraceptives for at least 2 months before the screening visit
 - 6.2. A non-hormonal intrauterine device or female condom with spermicide or contraceptive sponge with spermicide or diaphragm with spermicide or cervical cap with spermicide for at least 2 months before the screening visit
 - 6.3. A male sexual partner who agrees to use a male condom with spermicide
 - 6.4. A sterile sexual partneror:
True abstinence (i.e., refraining from heterosexual intercourse when this is in line with the preferred and usual lifestyle of the subject). Periodic abstinence (e.g., calendar, ovulation, symptothermal, post-ovulation methods), lactational amenorrhea, and withdrawal are not acceptable.
Women of non-child-bearing potential or in post-menopausal status for at least 1 year will be admitted.
For all women, pregnancy test result must be negative at screening and Day -1.

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

30 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

32

Total final enrolment

32

Key exclusion criteria

1. Electrocardiogram 12-leads (supine position): clinically significant abnormalities
2. Physical findings: clinically significant abnormal physical findings which could interfere with the objectives of the study
3. Laboratory analyses: clinically significant abnormal laboratory values indicative of physical illness
4. Application site: diseased-skin, skin wounds, abrasions, open injuries, tattoos, scars, moles or other abnormal pigmentation of the skin at the application site or any other physical/medical condition which could interfere with the objectives of the study
5. Allergy: ascertained or presumptive hypersensitivity to lidocaine or formulations' ingredients or both; ascertained or presumptive hypersensitivity to other amide local anaesthetics, such as bupivacaine, etidocaine, mepivacaine or prilocaine; ascertained or presumptive hypersensitivity to medical plasters; history of anaphylaxis to drugs or allergic reactions in general, which the Investigator considers may affect the outcome of the study
6. Diseases: significant history of renal, hepatic, gastrointestinal, cardiovascular, respiratory, skin, haematological, endocrine, immunological or neurological diseases that may interfere with the aim of the study
7. Medications: medications, including over the counter medications and herbal remedies for 2 weeks before the start of the study. Hormonal contraceptives for women will be allowed
8. 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
9. Blood donation: blood donations for 3 months before this study
10. Drug, alcohol, caffeine, tobacco: history of drug, alcohol [>1 drink/day for women and >2 drinks/day for men, defined according to the USDA Dietary Guidelines 2020-2025], caffeine (>5 cups coffee/tea/day) or tobacco abuse (≥ 10 cigarettes or electronic cigarettes/day)
11. Drug test: positive result at the urine drug test at screening or Day -1
12. Alcohol test: positive saliva alcohol test at screening or Day -1
13. Diet: abnormal diets (<1600 or >3500 kcal/day) or substantial changes in eating habits in the 4 weeks before this study; vegetarians and vegans
14. Pregnancy (women only): positive or missing pregnancy test at screening or Day -1, pregnant or lactating women.

Date of first enrolment

27/02/2025

Date of final enrolment

14/03/2025

Locations

Countries of recruitment

Italy

Switzerland

Study participating centre

CROSS Research S.A. - Phase I Unit

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Arzo

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Sponsor information

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Sponsor type

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Funder(s)

Funder type

Industry

Funder Name

IBSA Institut Biochimique S.A.

Results and Publications

Publication and dissemination plan

To date, there are no plans to public the study results in scientific journals.

Intention to publish date**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