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Study to evaluate the safety, absorption and elimination in the urine of a new diclofenac-based drug administered directly into the bladder

Submission date
19/01/2026

Recruitment status
No longer recruiting

Registration date
21/01/2026

Overall study status
Completed

Last Edited
15/10/2026

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The Sponsor, IBSA Institut Biochimique S.A., is investigating the safety, tolerability and pharmacokinetics (how the body affects the drug) of a new formulation of diclofenac sodium mixed with a diluent solution which will be instilled into the bladder of healthy women and women affected by recurrent urinary tract infections (UTIs) for the first time. The hypothesis is that, after the intravesical instillation, diclofenac can support the reduction of acute UTI episodes in patients affected by recurrent UTIs.

Who can participate?
Part A: healthy women aged 18-55 years
Part B: women with recurrent urinary tract infections (in remission) aged 18-55 years

What does the study involve?
Part A of the study:
The study will involve three consecutive groups (cohorts) of 8 healthy women. Each participant will receive either the investigational treatment or a sham control (saline solution), assigned at random.
Cohort 1: 1 ml of diclofenac (an antiinflammatory drug) + 45 ml of a diluent solution, or 46 ml of saline solution (sham control).
Cohort 2: 2 ml of diclofenac + 45 ml of solution, or 47 ml of saline solution.
Cohort 3: 3 ml of diclofenac + 45 ml of solution, or 48 ml of saline solution.
At first, only one participant in each cohort will receive the investigational drug, while another will receive the sham control. The following day, the medical team will assess whether the treatment is safe before proceeding with the remaining 6 participants (5 will receive the drug and 1 the sham control).
After each cohort, the study investigator will review any side effects and decide whether to move on to the next dose level. The study sponsor must approve each progression. Safety rules are in place to stop the study if necessary.

Part B of the study:
The safest dose identified in Part A will be tested in 6 women with recurrent urinary tract infections (without any active infection ongoing).

In both parts of the study, the drug will be administered on Day 1 at 08:00 (±1 hour), on an empty stomach. The physician will introduce the solution into the participants' bladder using a catheter.

What are the possible benefits and risks of participating?
No potential benefits are foreseen for the subjects participating in this study. However, a possible clinical benefit of this clinical study is to provide patients suffering from recurrent urinary tract infections with a potentially effective alternative to antibiotic treatment. The product under evaluation contains the widely used and well-known active ingredient diclofenac, which has an established favourable benefit-risk profile. Minimal risks are anticipated regarding tolerability at the instillation site.

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 2025 to June 2026

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, Public

Contact name
Dr Valeria Frangione

ORCID ID
https://orcid.org/0000-0003-0465-8953

Contact details
Via Pian Scairolo, 49
Pazzallo
Switzerland
6912
+41 (0)58 36 01 735
valeria.frangione@ibsa.ch

Type(s)
Principal investigator, Scientific

Contact name
Dr Milko Radicioni

ORCID ID
https://orcid.org/0000-0002-3940-8375

Contact details
Via F.A. Giorgioli, 14
Arzo
Switzerland
6864
+41 (0)91 64 04 450
milko.radicioni@croalliance.com

Additional identifiers

Sponsor's internal code
24CH-HyDi06

Study information

Scientific Title
Safety and pharmacokinetic study of a new diclofenac formulation administered to women by intravesical instillation
Single centre, two parts, safety, tolerability and pharmacokinetic study; Part A: randomized, single-blind, sham-controlled, single ascending dose study in healthy women; Part B: open-label, single-dose study in women affected by recurrent urinary tract infections

Study objectives
Part A:
The primary objective of Part A is to evaluate the safety and tolerability of three single ascending doses (1, 2 and 3 mL) of Diclofenac sodium 75 mg/mL solution in a diluent solution versus sham control, after intravesical administration to healthy women.
The secondary objective of study Part A is to evaluate the pharmacokinetic profile and parameters of diclofenac in plasma and urine after IMP administrations of 3 single ascending doses (1, 2 and 3 mL) of Diclofenac sodium 75 mg/mL solution in a diluent solution after intravesical administration to healthy women.

Part B:
The primary objective of study Part B is to evaluate the safety and tolerability of the highest dose of Diclofenac sodium 75 mg/mL solution in a diluent solution, considered as safe in study Part A, after intravesical administration to women with recurrent urinary tract infections in the quiescent phase.
The secondary objective of study Part B is to evaluate the pharmacokinetic profile and parameters of diclofenac in plasma and urine after intravesical administration of the highest safe dose (1, 2 or 3 mL) of Diclofenac sodium 75 mg/mL solution in a diluent solution after intravesical administration to women with recurrent urinary tract infections in the quiescent phase.

Ethics approval required

Ethics approval required

Ethics approval(s)
Approved 29/07/2025, Cantonal Ethics Committee (c/o Ufficio di sanità Via Orico 5, Bellinzona, 6501, Switzerland; +41 (0)91 814 30 57; dss-ce@ti.ch), ref: 2025-00808; Rif. CE 4840

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Single

Purpose
Basic science, Prevention, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Urinary tract infections (UTIs)

Interventions
The study is divided into two parts:
Part A: Healthy volunteers will receive a single dose of the investigational drug (at different concentrations: D1, D2, or D3) or a sham control, in a random order.
The study will involve three consecutive groups (cohorts) of 8 healthy women.
Cohort 1: 1 ml of diclofenac (an antiinflammatory drug) + 45 ml of a diluent solution, or 46 ml of saline solution (sham control).
Cohort 2: 2 ml of diclofenac + 45 ml of solution, or 47 ml of saline solution.
Cohort 3: 3 ml of diclofenac + 45 ml of solution, or 48 ml of saline solution.
At first, only one participant in each cohort will receive the investigational drug, while another will receive the sham control. The following day, the medical team will assess whether the treatment is safe before proceeding with the remaining 6 participants (5 will receive the drug and 1 the sham control).
After each cohort, the study investigator will review any side effects and decide whether to move on to the next dose level. The study sponsor must approve each progression. Safety rules are in place to stop the study if necessary.

Part B: Participants with recurrent urinary tract infections will receive an administration of the highest safe dose identified in Part A.

In both parts, the drug or sham control will be administered directly into the bladder through a urinary catheter on Day 1 at 08:00 (± 1 hour), and on an empty stomach.

Administration procedure:
Before instillation, the participant must urinate to completely empty the bladder.
The investigational drug will be prepared by mixing a diclofenac solution with a diluent, while the sham control will consist of sterile saline solution. Preparation will take place in a separate room outside the participant's view (to maintain the study blind).
After aseptic cleaning, the physician will instil the solution into the bladder using a urinary catheter while the participant is lying down.
After instillation, the participant must hold the urine for about 1 hour before emptying the bladder again.
To ensure that participants cannot guess which treatment they are receiving, a cover will be placed over their knees, as the color and consistency of the drug may differ from the sham control.

Safety measures:
The entire procedure will be performed using sterile gloves to avoid contamination.
The administration time and the time of the first urination after treatment will be recorded in the study documents.

Intervention Type
Drug

Phase
Phase I

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

Primary outcome(s)
1. Safety and tolerability measured using treatment-emergent adverse events, local tolerability at the instillation site, vital signs (blood pressure, heart rate), safety laboratory analysis, body weight, physical examination results at after single dose administration of the investigational product and sham control (only for study Part A)

Key secondary outcome(s)
1. Pharmacokinetic profile and parameters of diclofenac in plasma and urine measured using plasma diclofenac concentration-time profile and pharmacokinetic parameters (Cmax, AUC0-t, tmax, and, if feasible, %AUCextra, AUC0-∞, t1/2 and λZ); Urine diclofenac concentration-time profiles and pharmacokinetic parameters (Ae1-24, Ae1-4, Ae4-8, Ae8-12, Ae12-24, Fe1-t and Clr) at venous blood samples for PK on Days 1 and 2 at pre-dose (0), 0.5 (30 min), 1, 2, 3, 4, 6, 8, 10, 12, 14 and 24 h post-dose. Urine collection for evaluation of diclofenac concentration at following timepoints: Pre-dose , 1 h post-dose , 1-4 h post-dose, 4-8 h post-dose, 8-12 h post-dose, 12-24 h post-dose

Completion date
13/06/2026

Eligibility

Key inclusion criteria

1. Signed written informed consent before inclusion in the study.
2. Healthy women (Part A) or women with recurrent urinary tract infections (Part B), 18-55 years old inclusive
3. BMI: 18.5-30 kg/m2 inclusive
4. 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. 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 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 (IUD) 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 partner
6.5. True abstinence

Part B only:
Women suffering from recurrent UTIs, in line with the European Urology Association guideline and the standard clinical practice at the site, diagnosed by a primary care physician or medical specialist, and who are in the quiescent phase of the disease, i.e., who are not presenting any UTI acute-onset symptoms that typically include dysuria in conjunction with variable degrees of increased urinary urgency and frequency, haematuria, and new or worsening incontinence

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
Female

Total final enrolment
30

Key exclusion criteria
1. ECG with clinically significant abnormalities
2. Clinically significant abnormal physical findings, presence of mouth lesions/alteration and of any tongue piercings, partials, braces, dentures
3. Lab analyses with clinically significant abnormalities
4. Ascertained or presumptive hypersensitivity to the active principle and/or formulation

ingredients; history of anaphylaxis to drugs or allergic reactions
5. Significant diseases
6. Medications for 2 weeks before study start
7. Participation in the evaluation of any investigational product for 3 months before the study start
8. Blood donations for 3 months before this study
9. History of drug, alcohol, caffeine or tobacco abuse
10. Positive drug test at Day -1
11. Positive alcohol test at screening and Day -1
12. Abnormal diet
13. Positive or missing pregnancy test at screening or day-1, pregnant or lactating women

Date of first enrolment
23/10/2025

Date of final enrolment
11/06/2026

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

Funder Name
IBSA Institut Biochimique

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available