ISRCTN16167924 https://doi.org/10.1186/ISRCTN16167924

A study comparing a new Aceclofenac 100 mg film-coated tablet formulation to the marketed Gladio® 100 mg film-coated tablet formulation in healthy volunteers, looking at how well the new formulation delivers the medicine into the body (bioequivalence)

Submission date 03/11/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 10/11/2025	**Overall study status** Completed	
Last Edited 10/11/2025	**Condition category** Other	

Plain English summary of protocol

Background and study aims
The Sponsor, Abiogen Pharma S.p.A., has recently developed a new formulation of aceclofenac, that has the same dose and the same pharmaceutical form of the authorised product Gladio® 100 mg film-coated tablets.

The new formulation of this antinflammatory drug will be manufactured in a different facility and using a different manufacturing method in comparison with the currently approved ones of Gladio®, making a bioequivalence study between the two products necessary. This study will compare how well this new formulation delivers the medicine into the body, compared to the existing product Gladio® 100 mg film-coated tablets. The goal will be to see if both formulations result in similar levels of the medicine in the body when used by healthy men and women.

Who can participate?
Healthy men and women aged 18-55 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 will be conducted at the CROSS Research S.A. Phase I Unit Clinical Centre, in Arzo, Switzerland.
During each study period, the participants will be confined at the Phase I Unit from from the evening before the product administration until the evening of the day after for two consecutive periods.
Each study participant will receive a single oral dose of the test and reference products under

fasting conditions, in two study periods, with an interval of at least 7 days between the two administrations. Both test and reference products will be orally administered in the morning of study Day 1, at 8:00±1 h. Each investigational product will be swallowed whole, without crushing or chewing, with 150 mL of still mineral water by study participants.
Participants will have blood samples taken and vital parameters recorded at regular intervals. Physical examination and ECG will be performed at the beginning and at the end of the study.

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 will be performed during it.
On the basis of the aceclofenac safety profile, no potential risks are foreseen for the subjects enrolled in the present study.

Where is the study run from?
The study will be 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?
December 2024 to November 2025

Who is funding the study?
Abiogen Pharma S.p.A., Italy

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

Contact information

Type(s)
Scientific, Principal investigator

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 0916404450
clinic@croalliance.com

Type(s)
Public, Scientific

Contact name
Mrs Marina Accoto

ORCID ID
https://orcid.org/0009-0001-8085-1504

Contact details
Abiogen Pharma S.p.A.
Via Meucci, 36
Loc. Ospedaletto
Pisa
Italy
56121
+39.05.03.15.41.01
marina.accoto@abiogen.it

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Study CRO-PK-24-372 - Sponsor code ACEBIO/11

Study information

Scientific Title
Bioequivalence study of a new Aceclofenac 100 mg film-coated tablets formulation versus Gladio® 100 mg film-coated tablets formulation in healthy volunteers

Study objectives
The primary objective of the study is to evaluate the bioequivalence of the new Aceclofenac 100 mg film-coated tablets (test) versus the marketed Gladio® 100 mg film-coated tablets (reference), by assessing the rate and extent of absorption of aceclofenac after single-dose administration of the two products in healthy men and women under fasting conditions.

Secondary objectives of the study are the following:
- To evaluate the plasma pharmacokinetic parameters and profile of aceclofenac after single dose administration of the test and reference products;
- To collect safety and tolerability data of the test and reference products after single dose administration.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 21/08/2025, Canton Ticino Ethics Committee (c/o Ufficio di Sanità, Via Orico 5, Bellinzona, 6501, Switzerland; +41918143057; michaela.gutacker@ti.ch), ref: 2025-00855, 4846

Study design
Single-centre single-dose open-label randomized 2-way cross-over bioequivalence study

Primary study design

Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Healthy volunteers

Interventions
Test product:
Aceclofenac 100 mg film-coated tablets, Abiogen Pharma S.p.A., Italy

Reference product:
Gladio® 100 mg film-coated tablets, Abiogen Pharma S.p.A., Italy

Each study participant will receive a single oral dose of the test and reference products under fasting conditions, in two study periods, with a wash-out interval of at least 7 days between the two administrations, according to a 2-way cross-over randomised design. Each randomised subject will be allocated to a sequence of treatment administrations in the two study periods (T /R or R/T) according to a computer-generated randomisation list. The Sponsor will provide the Phase I Unit with individual subjects' kits prepared according to the randomisation list. The randomisation list will be provided to the investigator as well.

Both test and reference products will be orally administered on the morning of study Day 1, at 8: 00±1 h. Each investigational product will be swallowed whole, without crushing or chewing, with 150 mL of still mineral water by study participants.

Study participants will be confined at the clinical unit from the evening before the investigational product administration until the evening of the day after for two consecutive periods.

The safety of the products will be evaluated through the collection of treatment-emergent adverse events, physical examinations including body weight, vital signs (blood pressure and heart rate), ECG and routine haematology, blood chemistry and urinalysis laboratory tests.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
Test product Aceclofenac 100 mg film-coated tablets, Reference product Gladio® 100 mg film-coated tablets

Primary outcome(s)
Cmax and AUC0-t of plasma aceclofenac after single dose administration of test and reference. These parameters will be evaluated analysing venous blood samples collected from participants' forearm veins at the following times: at pre-dose (0) and 0.5 (30 min), 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8 and 12 h post-dose.

Key secondary outcome(s))
1. tmax, Frel and, if feasible, %AUCextra, AUC0-∞, t1/2 and λZ of plasma aceclofenac after single dose administration of test and reference. These parameters will be evaluated analysing venous blood samples collected from participants' forearm veins at the following times: at pre-dose (0) and 0.5 (30 min), 1, 1.5, 2, 2.5, 3, 3.5, 4, 5, 6, 8 and 12 h post-dose.
2. Treatment-emergent adverse events, vital signs (blood pressure, heart rate), physical examinations, body weight, clinical laboratory parameters, and ECG.
3. Vital signs will be evaluated through a sphygmomanometer at each visit. ECG (through an electrocardiograph), visual physical examination, and body weight (through an electronic weighing scale) will be evaluated at screening and final visits. Adverse events will be monitored throughout the whole study course.

Completion date
30/11/2025

Eligibility

Key inclusion criteria
1. Informed consent: signed written informed consent before inclusion in the study
2. Sex and Age: men/women, 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 50-99 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 partner
or:
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.
7. Contraception (men only): men will either be sterile or agree to use one of the following approved methods of contraception:
7.1. A male condom with spermicide
7.2. A sterile sexual partner or a partner in post-menopausal status for at least 1 year
7.3. Use by the female sexual partner of a non-hormonal intrauterine device, a female condom with spermicide, a contraceptive sponge with spermicide, a diaphragm with spermicide, a cervical cap with spermicide, or hormonal oral, implantable, transdermal, or injectable contraceptives for at least 2 months before the screening visit

or:
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, thermal symptoms, post-ovulation methods), female sexual partner lactational amenorrhea, and withdrawal are not acceptable.
Men must accept to inform their partners of their participation in the clinical study.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
55 years

Sex
All

Key exclusion criteria
1. Electrocardiogram (ECG) 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: serum alkaline phosphatase, alanine aminotransferase, aspartate aminotransferase, gamma-glutamyl transpeptidase, total bilirubin and creatine levels exceeding the upper limit of normality, as well as Estimated Glomerular Filtration Rate (eGFR) calculated using the Cockroft-Gault equation and normalized to an average surface area 1.73 m2 < 90 mL /min at screening, indicating abnormal liver and/or kidney function; 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 (in particular, acetylsalicylic acid, ibuprofen or other NSAIDs), which the Investigator considers may affect the outcome of the study
5. Diseases: significant history of renal, hepatic, gastrointestinal, cardiovascular, respiratory, skin, haematological, endocrine, immunological or neurological diseases (in particular, history of gastrointestinal bleeding or perforation related to previous NSAID therapy) that in the opinion of the Investigator may interfere with the aim of the study
6. Medications: medications, including over-the-counter (OTC) medications and herbal remedies, and in particular Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), for 2 weeks before the start of the study. Hormonal contraceptives for women will be allowed
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 [>1 drink/day for women and >2 drinks/day for men, defined according to the USDA Dietary Guidelines 2020-2025 (9)], caffeine (>5 cups coffee/tea/day) or tobacco abuse (10 cigarettes/day)
10. Urine drug test: positive result at the drug test at screening or Day-1
11. Alcohol saliva test: positive alcohol saliva test at screening or 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
13. Pregnancy (women only): positive or missing pregnancy test at screening or Day -1, pregnant or lactating women.

Date of first enrolment
04/11/2025

Date of final enrolment
07/11/2025

Locations

Countries of recruitment
Italy

Switzerland

Study participating centre
CROSS Research S.A. - Phase I Unit
Via F.A. Giorgioli, 14
Arzo
Switzerland
6864

Sponsor information

Organisation
Abiogen Pharma (Italy)

ROR
https://ror.org/03rkzne32

Funder(s)

Funder type
Industry

Funder Name
Abiogen Pharma S.p.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