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A single-dose, two-way crossover study to assess the absorption of two oral formulations of STC-15 and evaluate the effect of food on the pharmacokinetics of a single dose of STC-15 tablet in healthy participants

Submission date
20/10/2025

Recruitment status
Recruiting

Registration date
31/10/2025

Overall study status
Ongoing

Last Edited
30/10/2025

Condition category
Other

[X] 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
This study aims to evaluate the safety and tolerability of the experimental drug STC-15, which is being developed as a potential new treatment for advanced cancer. STC-15 capsules have been tested in humans with cancer before, and the sponsor has reformulated STC-15 as a tablet. STC-15 will be given to healthy volunteers to assess the safety and tolerability of STC-15 tablets, and assess how STC-15 moves through the body (pharmacokinetics; PK). The study also evaluates the effect of a high-fat, high-calorie meal in healthy participants on the PK of STC-15.

Who can participate?
Healthy adult volunteers.

What does the study involve?
A single group of participants will be enrolled in the study, which will be conducted in 2 parts over 3 dosing periods. Participants will receive single doses of the study drug for each dosing period, and the study drug will be a tablet or capsule administered orally with water under either fasting or fed conditions:

- Part 1: participants receive 50mg of STC-15 as a tablet and then, after a 5-day washout, will receive 30mg STC-15 as a capsule. The order in which these two dosing formulations are received will be random, meaning participants will receive a tablet, then a capsule, or a capsule, then a tablet.

- Part 2: participants will fast overnight for at least 10 hours, then consume a high-fat breakfast before dosing with a 50mg STC-15 tablet to evaluate the effect of food on STC-15.

Participants will remain in the unit for 16 nights, where dosing procedures and follow-up assessments will all occur while participants are in-house.

What are the possible benefits and risks of participating?
Although STC-15 has been tested in a previous patient population, we have limited information on the side effects that may be seen in humans. The tests that have been conducted in the previous human patient population and animals may give us an indication of what we may see when the study drug is given to humans.
As the primary purpose of this study is to evaluate the PK, Food Effect, safety and tolerability of STC-15 as a new formulation, it is anticipated that the frequency of adverse events will be lower than what is seen in the ongoing study in cancer patients. It is not possible to predict at this time whether you will receive all of, some of, or none of these side effects. It is also possible that you may experience side effects that are not listed in the list above.

Where is the study run from?
Scientia Clinical Research, Australia.

When is the study starting and how long is it expected to run for?
September 2025 to December 2025.

Who is funding the study?
Storm Therapeutics, UK.

Who is the main contact?
Christopher Argent, christopher.argent@scientiaclinicalresearch.com.au.

Contact information

Type(s)
Public, Scientific, Principal investigator

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Dr Christopher Argent

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
STC-15-25103

Study information

Scientific Title
An open-label, single oral dose, randomized, two-way crossover study to assess the relative bioavailability of two oral formulations of STC-15 and evaluate the effect of food on the pharmacokinetics of a single dose of STC-15 tablet in healthy participants

Study objectives
The primary objective of this study is to assess the bioavailability of a 50 mg STC-15 tablet (test) versus a 30 mg STC-15 capsule (reference) under fasted conditions in healthy participants.

The secondary objectives of this study are:
-To evaluate the effect of food on the pharmacokinetics (PK) of a single oral dose of 50 mg STC-15 tablet in healthy participants.
-To assess the safety and tolerability of 30 mg STC-15 capsule and 50 mg STC-15 tablet in healthy participants.

Ethics approval required
Ethics approval required

Ethics approval(s)
submitted 10/10/2025, Bellberry Human Research Ethics Committee (HREC) (Bellberry Limited, 196 Greenhill Road Eastwood, SA, 5063, Australia; +61 0883613222; bellberry@bellberry.com.au), ref: 2025-10-1681

Study design
Phase I single-dose open-label randomized 2-part 3-period study

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
This is a healthy volunteer study

Interventions
This is a study in healthy participants to compare the relative bioavailability of a 50 mg STC-15 tablet and a 30 mg STC-15 capsule (Part 1) and to assess the effect of food on the PK of a 50 mg STC-15 tablet (Part 2).

In Part 1 of the study, participants who meet all inclusion and none of the exclusion criteria will be randomly assigned 1:1 to receive a single dose of 50 mg STC-15 tablet (Treatment A) and 30 mg STC-15 capsule (Treatment B) orally under fasted conditions in 1 of 2 treatment sequences.

In Part 2 (Period 3) of the study, all participants will receive a single oral dose of a 50 mg STC-15 tablet after a high-fat, high-calorie breakfast.
The study will consist of a screening period, Check-in, 3 treatment periods, and an end-of-study (EOS) visit. There will be a washout of at least 120 hours between dosing in each period. The participants will be discharged from the clinic after at least 120 hours following dosing in Part 2.

The following PK parameters for STC-15 will be calculated as endpoints using standard non-compartmental methods: area under the plasma concentration-time curve from time 0 to the last quantifiable concentration (AUC0-t), area under the plasma concentration-time curve from time 0 extrapolated to infinity (AUC0-inf), maximum plasma concentration (Cmax), time to maximum observed plasma concentration (Tmax), elimination rate constant (Kel), terminal phase half-life (t1/2), apparent total body clearance (CL/F), and apparent volume of distribution (Vd/F). The dose-normalized PK parameters, such as AUC0-t/D, AUC0-inf/D, and Cmax/D, will also be calculated.

Safety and tolerability endpoints will include monitoring and recording of AEs, clinical laboratory test results (hematology, serum chemistry, and urinalysis), vital sign measurements, 12-lead ECG results, and physical examination findings.

Randomization process:
-Lead statistician will draft the Randomization Specification and Authorization Form (RSAF, i.e., randomization plan) and the randomization schedules using arbitrary.
-The stats team, including Senior Reviewer and RTSM team (Randomization Statistician and Randomization Quality Validator, who are independent and not involved in any other study activities but randomization process) will review the RSAF and randomization schedule.
-Once internal approvals are received, lead statistician will provide the RSAF and randomization schedules to Sponsor for review.
-Once Sponsor approval is received, the randomization schedule will be considered as actual version and released to the site.
-RTSM system is used

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
STC-15

Primary outcome(s)
PK parameters: AUC0-t, AUC0-inf, Cmax, Tmax, Kel, t1/2, CL/F, Vd/F. The dose normalized PK parameters (AUC0-t/D, AUC0-inf/D, and Cmax/D) will also be calculated using non compartmental analysis (NCA) at all PK timepoints from dosing through 120 hours for each period.

Key secondary outcome(s))
Safety and tolerability: AEs, clinical laboratory test results (hematology, serum chemistry, and urinalysis), vital sign measurements, 12-lead ECG results, and physical examination findings measured using patient records at screening (Day-28) through End of Treatment (Day 16).

Completion date
24/12/2025

Eligibility

Key inclusion criteria
1. Body mass index of 18 to 32 kg/m2
2. In good general health
3. Can swallow and retain oral medications

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. A history or presence of clinically significant allergies
2. Clinically significant heart disease, renal disease, or neurological disorder
3. History or presence of significant serious skin disease
4. Major abdominal surgery and/or significant bowel resection
5. Known psychiatric or substance abuse disorder
6. Poor venous access that would limit blood draws
7. Unacceptable organ function
8. Clinically significant abnormal ecg or blood pressure
9. Positive test result for hepatitis b surface antigen, hepatitis c virus antibody, or human immunodeficiency virus types 1 or 2 antibodies
10. Received any vaccine within 14 days
11. Current smoker or has used more than 5 cigarettes or equivalent amount of other nicotine-containing products per week
12. Participants under 18 will not be involved
13. Aboriginal or Torres Strait Islander participants will not be targeted.

Date of first enrolment
09/12/2025

Date of final enrolment
24/12/2025

Locations

Countries of recruitment
Australia

Study participating centre
Scientia Clinical Research Ltd
ABN 85 607 180 192
The Bright Building
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Randwick NSW
Australia
2031

Sponsor information

Organisation
Storm Therapeutics

Organisation
PPD Australia Pty Ltd

Funder(s)

Funder type
Industry

Funder Name
Storm Therapeutics

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes