Phase 1 Trial: 36024 (SYX-5219-101)

Submission date	Recruitment status	Prospectively registered
21/03/2025	Recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
21/03/2025	Deferred	Results
Last Edited	Condition category	Individual participant data
21/03/2025	Other	[X] Record updated in last year

Plain English summary of protocol

The Health Research Authority (HRA) has approved deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

Contact information

Type(s)

Scientific

Contact name

Dr Ravi Rao

Contact details

Sitryx Therapeutics Ltd, 101 Bellhouse Building, Magdalen Centre, Oxford Science Park Cambridge United Kingdom OX4 4GA +44 (0)1865 648401 ravi.rao@sitryx.com

Type(s)

Public

Contact name

Mr Gordon Dingwall

Contact details

Sitryx Therapeutics Ltd, 101 Bellhouse Building, Magdalen Centre, Oxford Science Park Cambridge United Kingdom OX4 4GA +44 (0)1865 648401 gordon.dingwall@sitryx.com

Type(s)

Principal Investigator

Contact name

Dr Annelize Koch

Contact details

Simbec-Orion Clinical Pharmacology, Merthyr Tydfil Industrial Park, Cardiff Road Merthyr Tydfil United Kingdom CF48 4DR +44 1443694313 annelize.koch@simbecorion.com

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

1011149

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

SYX-5219-101

Study information

Scientific Title

Phase 1 Trial: 36024 (SYX-5219-101)

Study objectives

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Ethics approval required

Ethics approval required

Ethics approval(s)

- 1. Approved 13/02/2025, Wales Research Ethics Committee 2 (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 2922 941119; Wales.REC2@wales.nhs.uk), ref: 25.WA.0017
- 2. Approved 18/02/2025, MHRA (MHRA, 10 South Colonnade, Canary Wharf, London, E14 4PU, United Kingdom; +44 (0) 20 3080 6000; info@mhra.gov.uk), ref: CTA 60473/0001/001-0001

Study design

A three-part first-in-human trial in up to 149 healthy participants and patients with Atopic Dermatitis (AD)

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Pharmaceutical testing facility, Other

Study type(s)

Other, Safety

Participant information sheet

Health condition(s) or problem(s) studied

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Interventions

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Intervention Type

Drug

Pharmaceutical study type(s)

Pharmacokinetic, Pharmacodynamic

Phase

Phase I

Drug/device/biological/vaccine name(s)

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Primary outcome measure

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Secondary outcome measures

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Overall study start date

30/09/2024

Completion date

31/08/2026

Eligibility

Key inclusion criteria

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Participant type(s)

Healthy volunteer, Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

149

Key exclusion criteria

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Date of first enrolment

26/02/2025

Date of final enrolment

30/06/2026

Locations

Countries of recruitment

United Kingdom

Wales

Study participating centre Simbec Research Limited

Simbec House Merthyr Tydfil Industrial Park Merthyr Tydfil Industrial Park Pentrebach Merthyr Tydfil Mid Glamorgan United Kingdom CF48 4DR

Sponsor information

Organisation

Sitryx Therapeutics Ltd.

Sponsor details

101 Bellhouse Building, Magdalen Centre, Oxford Science Park Cambridge England United Kingdom OX4 4GA

gordon.dingwall@sitryx.com

Sponsor type

Industry

Website

https://www.sitryx.com/

Funder(s)

Funder type

Industry

Funder Name

Sitryx Therapeutics Ltd.

Results and Publications

Publication and dissemination plan

Full trial details will be published up to 30 months after the end of the trial. Publication of some trial details is deferred because of the high commercial sensitivity of this phase I study and the negligible benefit to the public of phase I information. Results will be posted on or after the date of publication of full trial details.

Intention to publish date

20/12/2029

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study are not expected to be made available because of their high commercial sensitivity and the negligible benefit to the public of publication of results of non-therapeutic clinical trials.

IPD sharing plan summary

Not expected to be made available