ISRCTN80838388 https://doi.org/10.1186/ISRCTN80838388

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

Submission date
21/03/2025

Recruitment status
Recruiting

Registration date
21/03/2025

Overall study status
Deferred

Last Edited
21/03/2025

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[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