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

Submission date 21/03/2025	**Recruitment status** Recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 21/03/2025	**Overall study status** Deferred	[ ] Statistical analysis plan [ ] Results
Last Edited 21/03/2025	**Condition category** Other	[ ] Individual participant data [ ] 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.

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
1011149

Protocol serial number
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

Study type(s)
Other, Safety

Health condition(s) or problem(s) studied
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Interventions
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Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
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Primary outcome(s)
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.

Key secondary outcome(s))
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Completion date
31/08/2026

Eligibility

Key inclusion criteria
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Participant type(s)
Healthy volunteer, Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

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
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United Kingdom
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Sponsor information

Organisation
Sitryx Therapeutics Ltd.

Funder(s)

Funder type
Industry

Funder Name
Sitryx Therapeutics Ltd.

Results and Publications

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