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Phase 1/2a Trial: 36919 (T7-010-02)

Submission date 28/08/2026	**Recruitment status** Recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [X] Record updated in last year
Registration date 28/08/2026	**Overall study status** Deferred	
Last Edited 08/09/2026	**Condition category** Other	

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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Public, Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
1014307

Study information

Scientific Title
Phase 1/2a Trial: 36919 (T7-010-02) [Full scientific title to be added on or before the deferral expiry date]

Acronym
T7-010-02

Study objectives
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Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 14/08/2026, Wales Research Ethics Committee 2 (Health and Care Research Wales Floor 4, Crown Building Cathays Park, Cardiff, CF10 3NQ, United Kingdom; no telephone number provided; Wales.REC2@wales.nhs.uk), ref: 26/WA/0158

2. Approved 14/08/2026, MHRA (MHRA, 10 South Colonnade, Canary Wharf, London, E14 4PU, United Kingdom; +44 (0) 20 3080 6000; info@mhra.gov.uk), ref: CTA 62527/0001/001-0001

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Sequential

Purpose
Safety, Tolerability, PK and PD

Study type(s)

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

Phase
Phase I/II

Drug/device/biological/vaccine name(s)
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Primary outcome(s)
1. [Outcome] measured using [measure] at [timepoint]. 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)

Completion date
14/07/2027

Eligibility

Key inclusion criteria
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Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
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Date of first enrolment
10/09/2026

Date of final enrolment
13/04/2027

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Simbec-Orion Clinical Pharmacology (AKA Simbec Research Ltd)
Simbec-Orion Clinical Pharmacology, Merthyr Tydfil Industrial Park, Cardiff Road
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Sponsor information

Organisation
T7 Therapeutics Inc

Funder(s)

Funder type

Funder Name
T7 Therapeutics Inc

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available