ISRCTN16055614 https://doi.org/10.1186/ISRCTN16055614

Phase I trial; HMR code: 24-003

Submission date 05/08/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 12/08/2024	**Overall study status** Deferred	[_] Statistical analysis plan [_] Results
Last Edited 06/01/2025	**Condition category** Other	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol
The sponsor has confirmed that the trial meets the criteria for 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
1010220

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 1010220; HMR code: 24-003; Sponsor code: SLG-TED-101

Study information

Scientific Title
Phase I trial; HMR code: 24-003 [The full scientific title will be published within 30 months after the end of the trial]

Study objectives
The sponsor has confirmed that the trial meets the criteria for 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.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 30/07/2024, London – Surrey Borders Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, United Kingdom; +44 207 104 8057; surreyborders.rec@hra.nhs.uk), ref: 24/LO/0492

Study design
Pharmacokinetic and bioavailability study in up to 20 healthy volunteers

Primary study design
Interventional

Secondary study design

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format

Health condition(s) or problem(s) studied
Healthy volunteers

Interventions
The sponsor has confirmed that the trial meets the criteria for 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.

Intervention Type
Drug

Pharmaceutical study type(s)
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Phase
Phase I

Drug/device/biological/vaccine name(s)
The sponsor has confirmed that the trial meets the criteria for 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.

Primary outcome measure
The sponsor has confirmed that the trial meets the criteria for 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.

Secondary outcome measures
The sponsor has confirmed that the trial meets the criteria for 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.

Overall study start date
05/06/2024

Completion date
08/08/2025

Eligibility

Key inclusion criteria
Healthy volunteer

Participant type(s)

Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
Up to 20

Key exclusion criteria
The sponsor has confirmed that the trial meets the criteria for 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.

Date of first enrolment
14/08/2024

Date of final enrolment
08/05/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Hammersmith Medicines Research Limited
Cumberland Avenue
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Sponsor information

Organisation
Sling Therapeutics, Inc.

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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Sling Therapeutics, Inc.

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 may be posted on or after the date of publication of full trial details.

Intention to publish date
08/02/2028

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