ISRCTN58651193 https://doi.org/10.1186/ISRCTN58651193

Phase I trial, HMR code: 21-014

Submission date 18/05/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 25/05/2022	**Overall study status** Deferred	[_] Statistical analysis plan [_] Results
Last Edited 27/03/2024	**Condition category** Other	[_] Individual participant data [_] 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

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2022-000511-31

IRAS number
1005035

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 1005035; HMR code: 21-014; Sponsor code: SLN501-001

Study information

Scientific Title
Phase I trial, HMR code: 21-014 [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
Old ethics approval format

Ethics approval(s)
1. Approved 19/05/2022, London–Brent (80 London Road, Skipton House, SE1 6LH, UK; +44 (0)20 7104 8128; brent.rec@hra.nhs.uk), ref: 22/LO/0242
2. Approved 23/05/2022, MHRA (10 South Colonnade, Canary Wharf, London, E14 4PU, UK; +44 (0)20 3080 6000; info@mhra.gov.uk), ref: CTA 49938/0005/001-0001

Study design
First-in-human safety, pharmacokinetics and pharmacodynamics trial in up to 32 healthy volunteers

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format.

Health condition(s) or problem(s) studied
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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

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
21/03/2022

Completion date
14/10/2023

Eligibility

Key inclusion criteria
Healthy human volunteer

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
Up to 32

Key exclusion criteria

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Date of first enrolment
30/05/2022

Date of final enrolment
14/10/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
HMR
Cumberland Avenue
Park Royal
London
United Kingdom
NW10 7EW

Sponsor information

Organisation
Silence Therapeutics (United Kingdom)

Sponsor details
72 Hammersmith Road
London
England
United Kingdom
W14 8TH
+44 (0)20 3457 6900
LEGAL@silence-therapeutics.com

Sponsor type
Industry

Website
https://www.silence-therapeutics.com/

ROR
https://ror.org/03p3e4237

Funder(s)

Funder type
Industry

Funder Name
Silence Therapeutics

Alternative Name(s)
Silence Therapeutics plc

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Trial information and summary results 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 1 study and the negligible benefit to the public of Phase I information.

Intention to publish date
30/06/2026

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