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

Contact name
Dr Malcolm Boyce

ORCID ID
https://orcid.org/0000-0001-8807-612X

Contact details
HMR, Cumberland Avenue
London
United Kingdom
NW10 7EW
+44 (0)20 8961 4130
rec@hmrlondon.com

Additional identifiers

Clinical Trials Information System (CTIS)
2022-000511-31

Integrated Research Application System (IRAS)
1005035

Protocol serial number
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

Study type(s)
Other

Health condition(s) or problem(s) studied
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.

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(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.

Key secondary outcome(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.

Completion date
14/10/2023

Eligibility

Key inclusion criteria
Healthy human volunteer

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
30/05/2022

Date of final enrolment
14/10/2023

Locations

Countries of recruitment
United Kingdom

England

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

Sponsor information

Organisation
Silence Therapeutics (United Kingdom)

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

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