ISRCTN24909354 https://doi.org/10.1186/ISRCTN24909354

Phase I trial: Parexel Code: PXL277433

Submission date 15/11/2023	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 16/11/2023	**Overall study status** Deferred	[ ] Statistical analysis plan [ ] Results
Last Edited 16/11/2023	**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.

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
1007366

Protocol serial number
Parexel PXL27743

Study information

Scientific Title
Phase I trial: Parexel Code: PXL277433 [The full scientific title will be published within 30 months after the end of the trial]

Study objectives
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Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 02/08/2023, Brent Research Ethics Committee Health Research Authority (2 Redman Place Stratford, London, E20 1JQ, United Kingdom; +44 (0)20 7104 8128, +44 (0)207 104 8131; brent.rec@hra.nhs.uk), ref: 23/LO/0321; The HRA has approved deferral of publication of trial details.

2. Approved 17/08/2023, MHRA (10 South Colonnade, Canary Wharf, London, E14 4PU, United Kingdom; +44 (0)20 3080 6000; info@mhra.gov.uk), ref: CTA 29969/0159/001-0001; The HRA has approved deferral of publication of trial details

Primary study design
Interventional

Study design
First-in-man safety, pharmacokinetics and pharmacodynamics trial in 88 healthy volunteers

Study type(s)
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)
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Key secondary outcome(s)
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Completion date
30/08/2024

Eligibility

Key inclusion criteria
Healthy human volunteers

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
All

Key exclusion criteria
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Date of first enrolment
22/08/2023

Date of final enrolment
30/08/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Parexel International; Parexel Early Phase Clinical Unit
Northwick Park Hospital
Watford Road
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Sponsor information

Organisation
Sanofi-Aventis Recherche & Développement

Funder(s)

Funder type
Industry

Funder Name
Sanofi-Aventis Recherche & Développement

Results and Publications

Individual participant data (IPD) sharing plan
Qualified researchers may request access to patient-level data and related study documents including the clinical study report, study protocol with any amendments, blank case report form, statistical analysis plan, and dataset specifications. Patient-level data will be anonymized and study documents will be redacted to protect the privacy of trial participants. Further details on Sanofi's data sharing criteria, eligible studies, and process for requesting access can be found at: https://vivli.org

IPD sharing plan summary
Available on request