ISRCTN48262326 https://doi.org/10.1186/ISRCTN48262326

Deferred registration: Fortrea code 780279

Submission date 03/07/2026	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 03/07/2026	**Overall study status** Deferred	[_] Statistical analysis plan [_] Results
Last Edited 03/07/2026	**Condition category** Other	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol
The Health Research Authority has approved a deferral. Full details will be added to the trial record on or before the deferral expiry date.

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
1013562

Study information

Scientific Title
Deferred registration: Fortrea code 780279 [Full scientific title to be added on or before the deferral expiry date]

Study objectives

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Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 17/04/2026, London - Riverside REC (2nd Floor 2 Redman Place Stratford, London, E20 1JQ, United Kingdom; no telephone number provided; riverside.rec@hra.nhs.uk), ref: 26/LO/0071

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Crossover

Purpose
Pharmacokinetic

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

Drug/device/biological/vaccine name(s)
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Primary outcome(s)

1. The Health Research Authority has approved a deferral. Full details will be added to the trial record on or before the deferral expiry date. [Outcome] measured using [measure] at [timepoint]

Key secondary outcome(s)

Completion date
07/10/2026

Eligibility

Key inclusion criteria
The Health Research Authority has approved a deferral. Full details will be added to the trial record (including age limits) on or before the deferral expiry date

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
0 Years

Upper age limit
1 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
The Health Research Authority has approved a deferral. Full details will be added to the trial record on or before the deferral expiry date

Date of first enrolment
28/08/2026

Date of final enrolment
28/08/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Fortrea Clinical Research Unit (Drapers Yard)
Drapers Yard, Marshall St, Holbeck
Leeds
England
LS11 9EH

Sponsor information

Organisation
Sanofi (France)

ROR
https://ror.org/02n6c9837

Funder(s)

Funder type

Funder Name
Sanofi France

Alternative Name(s)
Sanofi S.A., Sanofi, Sanofi-Aventis, Sanofi-Synthélabo

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
France

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available