ISRCTN49135540 https://doi.org/10.1186/ISRCTN49135540

Phase I trial code: PKM17308

Submission date 15/11/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 17/11/2023	**Overall study status** Deferred	[_] Statistical analysis plan [_] Results
Last Edited 17/11/2023	**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)
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
1005387

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 1005387

Study information

Scientific Title
Phase I trial code: PKM17308

Study objectives
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Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 10/06/2022, North West - Greater Manchester Central Research Ethics Committee (3rd Floor Barlow House 4 Minshull Street, Manchester, LM1 3DZ, United Kingdom; +44 (0)207 104 8244, (0)207 104 8004; gmcentral.rec@hra.nhs.uk), ref: 22/NW/0258

Study design
Pharmacokinetics (PK) study in 12 healthy participants

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format.

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

Interventions
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Intervention Type
Drug

Pharmaceutical study type(s)
Pharmacokinetic, Pharmacogenetic, Safety

Phase
Phase I

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

Secondary outcome measures
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Overall study start date
28/04/2022

Completion date
15/06/2023

Eligibility

Key inclusion criteria
Healthy human volunteer

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit

18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
12

Key exclusion criteria
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Date of first enrolment
24/04/2023

Date of final enrolment
15/06/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Quotient Sciences - Nottingham
Mere Way, Ruddington
Nottingham
United Kingdom
NG11 6JS

Sponsor information

Organisation
Sanofi-Aventis Recherche & Développement

Sponsor details
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None provided
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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Sanofi-Aventis Recherche & Développement

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

Intention to publish date
08/12/2025

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
Not expected to be made available