ISRCTN40495811 https://doi.org/10.1186/ISRCTN40495811

Phase I Trial: RD 785.35736 (ADR-UK-23-1)

Submission date 12/04/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 12/04/2024	**Overall study status** Deferred	[_] Statistical analysis plan [_] Results
Last Edited 12/04/2024	**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.

Study website
Not Applicable

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
1008056

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
ADR-UK-23-1, IRAS 1008056

Study information

Scientific Title
Phase I Trial: RD 785.35736 (ADR-UK-23-1)

Acronym
ADR-UK-23-1

Study objectives
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.

Ethics approval required

Ethics approval required

Ethics approval(s)
Approved 16/01/2024, Wales Research Ethics Committee 2 (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 (0)2922 941119; Wales.REC2@wales.nhs.uk), ref: 23.WA.0204

Study design
Three-part open-label study in up to 90 healthy participants

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Pharmaceutical testing facility

Study type(s)
Other, Safety

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Interventions
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Intervention Type
Drug

Pharmaceutical study type(s)
Pharmacokinetic

Phase
Phase I

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

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Secondary outcome measures
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.

Overall study start date
10/02/2023

Completion date
23/11/2024

Eligibility

Key inclusion criteria
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Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
90

Key exclusion criteria
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Date of first enrolment
30/04/2024

Date of final enrolment

17/11/2024

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Simbec Research Limited
Simbec House Merthyr Tydfil Industrial Park
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Sponsor information

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Industry

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Funder(s)

Funder type
Industry

Funder Name
Theravia

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
23/05/2027

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