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Phase 1 Trial: RD 798.35832 (KH-001-01-01)

Submission date 24/11/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 27/11/2023	**Overall study status** Deferred	[_] Statistical analysis plan [_] Results
Last Edited 27/11/2023	**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

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Additional identifiers

EudraCT/CTIS number
2023-000058-83

IRAS number
1007122

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
KH-001-01-01, IRAS 1007122

Study information

Scientific Title
Phase 1 Trial: RD 798.35832 (KH-001-01-01)

Study objectives
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Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 22/09/2023, Wales Research Ethics Committee 2 (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 2922 941119; Wales.REC2@wales.nhs.uk), ref: 23/WA/0040

2. Approved 23/10/2023, MHRA (10 South Colonnade, Canary Wharf, London, E14 4PU, United Kingdom; +44 (0) 20 3080 6000; info@mhra.gov.uk), ref: CTA 56572/0001/001-0001

Study design
A five-part first-in-human trial in up to 120 healthy participants

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Pharmaceutical testing facility, Other

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
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
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
06/10/2022

Completion date
30/05/2024

Eligibility

Key inclusion criteria
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Participant type(s)

Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
64 Years

Sex
Male

Target number of participants
120

Key exclusion criteria
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Date of first enrolment
14/11/2023

Date of final enrolment
17/05/2024

Locations

Countries of recruitment
United Kingdom

Wales

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

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Sponsor type
Industry

Website
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Funder(s)

Funder type
Industry

Funder Name
Kanna Health Limited

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
31/12/2025

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