ISRCTN98553810 https://doi.org/10.1186/ISRCTN98553810

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

Submission date
24/11/2023

Recruitment status
No longer recruiting

Registration date
27/11/2023

Overall study status
Deferred

Last Edited
27/11/2023

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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

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Additional identifiers

Clinical Trials Information System (CTIS)
2023-000058-83

Integrated Research Application System (IRAS)
1007122

Protocol serial number
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

Study type(s)
Other, Safety

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

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
30/05/2024

Eligibility

Key inclusion criteria
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Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
64 years

Sex
Male

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
Pentrebach
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United Kingdom
CF48 4DR

Sponsor information

Organisation
Kanna Health Limited

Funder(s)

Funder type
Industry

Funder Name
Kanna Health Limited

Results and Publications

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