ISRCTN81436702 https://doi.org/10.1186/ISRCTN81436702

Phase 1 Trial: RD 792.34234 (SPON1896-22)

Submission date 23/01/2023	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 24/01/2023	**Overall study status** Deferred	[ ] Statistical analysis plan [ ] Results
Last Edited 24/01/2023	**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.

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Additional identifiers

EudraCT/CTIS number
2022-002562-33

IRAS number
1006242

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
SPON1896-22, IRAS 1006242

Study information

Scientific Title
Phase 1 Trial: RD 792.34234 (SPON1896-22) [The full scientific title will be published within 30 months after the end of the trial]

Study objectives
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Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 06/12/2022, Wales Research Ethics Committee 1 (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44 (0)2920 230457; Wales.REC1@wales.nhs.uk), ref: 22/WA/0320
2. Approved 22/12/2022, MHRA (10 South Colonnade, Canary Wharf, London, E14 4PU, UK; +44 (0)20 3080 6000; info@mhra.gov.uk), ref: CTA 21323/0056/001-0001

The HRA has approved deferral of publication of trial details.

Study design
A three-part first-in-human trial in up to 116 healthy participants

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

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

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
20/06/2022

Completion date
03/11/2023

Eligibility

Key inclusion criteria
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Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
116

Key exclusion criteria
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Date of first enrolment
09/01/2023

Date of final enrolment
29/09/2023

Locations

Countries of recruitment
United Kingdom

Wales

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

Organisation
Cardiff University

Sponsor details
Research Integrity, Governance and Ethics (RIGE) Team Research and Innovation Services
Cardiff Joint Research Office
2nd Floor, Lakeside Building
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Sponsor type
University/education

Website
https://www.cardiff.ac.uk/medicines-discovery

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust

Alternative Name(s)
Wellcome, WT

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

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
04/04/2025

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
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No