

Phase 1 Trial: RD 792.34234 (SPON1896-22)

Submission date 23/01/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 24/01/2023	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 24/01/2023	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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)

Scientific

Contact name

Mrs MDI Neuroscience Portfolio Manager

Contact details

Cardiff University
Medicines Discovery Institute
Main Building
Park Place
Cardiff
United Kingdom
CF10 3AT
+ 44 (0)2922 511 095
swettenhamj@cardiff.ac.uk

Type(s)

Public

Contact name

Mrs MDI Neuroscience Portfolio Manager

Contact details

Cardiff University
Medicines Discovery Institute
Main Building

Park Place
Cardiff
United Kingdom
CF10 3AT
+ 44 (0)2922 511 095
swettenhamj@cardiff.ac.uk

Type(s)

Principal investigator

Contact name

Dr Annelize Koch

Contact details

Simbec-Orion Clinical Pharmacology
Merthyr Tydfil Industrial Park
Cardiff Road
Merthyr Tydfil
United Kingdom
CF48 4DR
+44 (0)1443694313
annelize.koch@simbecorion.com

Additional identifiers

Clinical Trials Information System (CTIS)

2022-002562-33

Integrated Research Application System (IRAS)

1006242

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Other

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

03/11/2023

Eligibility

Key inclusion criteria

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Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

Mid Glamorgan

United Kingdom

CF48 4DR

Sponsor information

Organisation

Cardiff University

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

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