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Phase 1 Trial: RD 799.35751 (ETH47-101)

Submission date 04/12/2023	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 04/12/2023	**Overall study status** Deferred	
Last Edited 04/12/2023	**Condition category** Other	

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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
1007882

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
ETH47-101, IRAS 1007882

Study information

Scientific Title
Phase 1 Trial: RD 799.35751 (ETH47-101)

Study objectives
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Ethics approval required
Ethics approval required

Ethics approval(s)

1. Approved 22/11/2023, Wales Research Ethics Committee 2 (Wales Research Ethics Committee 2, Health and Car 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.0186

2. Approved 22/11/2023, MHRA (MHRA, 10 South Colonnade, Canary Wharf, London, E14 4PU, United Kingdom; +44 (0)20 3080 6000; info@mhra.gov.uk), ref: CTA 56586/0001/001-0001

Study design
First-in-human trial in healthy participants

Primary study design
Interventional

Secondary study design
Randomised controlled 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, Pharmacodynamic

Phase
Phase I

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

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Secondary outcome measures
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Overall study start date
23/02/2023

Completion date
30/04/2024

Eligibility

Key inclusion criteria
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Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
Both

Target number of participants
88

Key exclusion criteria
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Date of first enrolment
29/11/2023

Date of final enrolment

09/04/2024

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

Organisation
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Sponsor type
Industry

Website
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https://ror.org/05mz52w65

Funder(s)

Funder type
Industry

Funder Name
Ethris GmbH

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
31/10/2026

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