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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

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
1007882

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

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
30/04/2024

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
55 years

Sex
All

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
Merthyr Tydfil Industrial Park
Pentrebach
Merthyr Tydfil

Mid Glamorgan
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Sponsor information

Organisation
Ethris (Germany)

ROR
https://ror.org/05mz52w65

Funder(s)

Funder type
Industry

Funder Name
Ethris GmbH

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes