ISRCTN15391202 https://doi.org/10.1186/ISRCTN15391202

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

Contact name
Mr Nigel Tomkinson

Contact details
Ethris GmbH
Semmelweisstrasse 3
Planegg
Munich
Germany
82152
-
info@ethris.com

Type(s)
Public

Contact name
Mr Nigel Tomkinson

Contact details
Ethris GmbH
Semmelweisstrasse 3
Planegg
Munich

Germany
82152
-
info@ethris.com

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)1443 694313
annelize.koch@simbecorion.com

Additional identifiers

Integrated Research Application System (IRAS)
1007882

Protocol serial number
ETH47-101

Study information

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

Study objectives
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.

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

Primary study design
Interventional

Study design
First-in-human trial in healthy participants

Study type(s)
Other, Safety

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

Interventions
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.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
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.

Primary outcome(s)
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.

Key secondary outcome(s)
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.

Completion date
30/04/2024

Eligibility

Key inclusion criteria
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.

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
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.

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
United Kingdom
CF48 4DR

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