

Phase 1 Trial: RD 799.35751 (ETH47-101)

Submission date 04/12/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/12/2023	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 04/12/2023	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

Mr Nigel Tomkinson

Contact details

Ethris GmbH
Simmelweisstrasse 3
Planegg
Munich
Germany
82152
-
info@ethris.com

Type(s)

Public

Contact name

Mr Nigel Tomkinson

Contact details

Ethris GmbH
Simmelweisstrasse 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

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

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