ISRCTN82038982 https://doi.org/10.1186/ISRCTN82038982

Phase I Trial: RD 783.35406 (RXC008-0001)

Submission date 04/03/2024	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 04/03/2024	**Overall study status** Deferred	[ ] Statistical analysis plan [ ] Results
Last Edited 04/03/2024	**Condition category** Other	[ ] Individual participant data [ ] 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.

Study website
Not applicable

Contact information

Type(s)
Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
1008652

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
RXC008-0001, IRAS 1008652

Study information

Scientific Title
Phase I Trial: RD 783.35406 (RXC008-0001)

Acronym
Nil known

Study objectives
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Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 20/12/2023, Wales Research Ethics Committee 2 (Health and Care 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.0280

2. Approved 27/12/2023, MHRA (MHRA, 10 South Colonnade, Canary Wharf, London, E14 4PU, United Kingdom; +44 (0)20 3080 6000; info@mhra.gov.uk), ref: CTA 48121/0006/001-0001

Study design
A three-part first-in-human trial in up to 104 healthy participants and patients with strictures due to Crohn’s Disease

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

Health condition(s) or problem(s) studied
Healthy volunteers and patients with strictures due to Crohn’s Disease

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
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.

Overall study start date
27/09/2023

Completion date
05/09/2024

Eligibility

Key inclusion criteria
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Participant type(s)
Healthy volunteer, Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
Male

Target number of participants
104

Key exclusion criteria
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Date of first enrolment
25/01/2024

Date of final enrolment
07/08/2024

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre

Simbec Research Limited
Simbec House Merthyr Tydfil Industrial Park
Merthyr Tydfil Industrial Park
Pentrebach
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Sponsor information

Organisation
Redx Pharma (United Kingdom)

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Sponsor type
Industry

Website
https://www.redxpharma.com/

ROR
https://ror.org/04wysdg63

Funder(s)

Funder type
Industry

Funder Name
Redx Pharma Plc

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
31/12/2025

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
Not expected to be made available