

Phase I trial code: RD 787.36057 (MTX325-101)

Submission date 05/03/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/03/2024	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/02/2025	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

Dr Suhail Nurbhai

Contact details

Mission Therapeutics Ltd., The Glenn Berge Building, Babraham Research Campus
Cambridge
United Kingdom
CB22 3FH
+44 (0) 1223 867926
snurbhai@missiontherapeutics.com

Type(s)

Public

Contact name

Ms Natalie Jones

Contact details

Mission Therapeutics Ltd., The Glenn Berge Building, Babraham Research Campus
Cambridge
United Kingdom
CB22 3FH
+44 (0) 7462 135809
njones@missiontherapeutics.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)1443694313
annelize.koch@simbecorion.com

Additional identifiers**Clinical Trials Information System (CTIS)**

2024-517310-15

Integrated Research Application System (IRAS)

1008552

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

MTX325-101, IRAS 1008552

Study information**Scientific Title**

Phase I trial code: RD 787.36057 (MTX325-101)

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 21/11/2023, 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/0258
2. approved 30/11/2023, MHRA (MHRA, 10 South Colonnade, Canary Wharf,, London, E14 4PU, United Kingdom; +44 (0) 20 3080 6000; info@mhra.gov.uk), ref: CTA 56125/0002/001-0001

Study design

A five-part first-in-human trial in up to 158 healthy participants and patients with mild to moderate Parkinson's Disease

Primary study design

Interventional

Study type(s)

Safety

Health condition(s) or problem(s) studied

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.

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

09/05/2026

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, Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

75 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

06/02/2024

Date of final enrolment

14/11/2025

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

Mission Therapeutics Ltd.

Funder(s)

Funder type

Industry

Funder Name

Mission Therapeutics Ltd.

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

Not expected to be made available