

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

Submission date 05/03/2024	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/03/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/03/2024	Condition category Not Applicable	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English Summary

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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Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

1008552

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

MTX325-101, IRAS 1008552

Study information

Scientific Title

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Study hypothesis

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Ethics approval required

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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

Secondary study design

Randomised controlled trial

Study setting(s)

Pharmaceutical testing facility

Study type(s)

Safety

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Condition

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Interventions

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Intervention Type

Drug

Pharmaceutical study type(s)

Pharmacokinetic, Pharmacogenetic

Phase

Phase I

Drug/device/biological/vaccine name(s)

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Primary outcome measure

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Secondary outcome measures

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Overall study start date

09/08/2023

Overall study end date

09/05/2026

Eligibility

Participant inclusion criteria

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Participant type(s)

Healthy volunteer, Patient

Age group

Mixed

Lower age limit

18 Years

Upper age limit

75 Years

Sex

Both

Target number of participants

158

Participant exclusion criteria

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Recruitment start date

06/02/2024

Recruitment end date

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
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United Kingdom
CF48 4DR

Sponsor information

Organisation

Mission Therapeutics Ltd.

Sponsor details

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Sponsor type

Industry

Website

<https://missiontherapeutics.com/>

Funder(s)

Funder type

Industry

Funder Name

Mission Therapeutics Ltd.

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

31/12/2026

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