ISRCTN20898392 https://doi.org/10.1186/ISRCTN20898392

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

Submission date 05/03/2024	**Recruitment status** Recruiting	[_] Prospectively registered [_] Protocol
Registration date 06/03/2024	**Overall study status** Deferred	[_] Statistical analysis plan [_] Results
Last Edited 06/02/2025	**Condition category** Other	[_] Individual participant data [X] 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.

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Additional identifiers

EudraCT/CTIS number
2024-517310-15

IRAS number
1008552

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
MTX325-101, IRAS 1008552

Study information

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

Study objectives
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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

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.

Health condition(s) or problem(s) studied
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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

Completion date
09/05/2026

Eligibility

Key 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

Key exclusion criteria
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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
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Sponsor information

Organisation
Mission Therapeutics Ltd.

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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