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

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

Submission date 05/03/2024	**Recruitment status** No longer 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 [ ] 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

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
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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

Study type(s)
Safety

Health condition(s) or problem(s) studied
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Interventions
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Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
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Primary outcome(s)
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Key secondary outcome(s))
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Completion date
09/05/2026

Eligibility

Key inclusion criteria
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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
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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
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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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes