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 [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 06/03/2024	**Overall study status** Deferred	
Last Edited 04/06/2026	**Condition category** Other	

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
c/o Ensors Chartered Accountants, Victory House Vision Park, Chivers Way
Histon
United Kingdom
CB24 9ZR
+44 (0) 1223 867926
snurbhai@missiontherapeutics.com

Type(s)
Public

Contact name
Ms Sarah Fritchley

Contact details
c/o Ensors Chartered Accountants, Victory House Vision Park, Chivers Way
Histon
United Kingdom
CB24 9ZR
+44 (0) 7462 135809
sfritchley@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

Type(s)
Public

Contact name
Ms Francesca Pinocci

Contact details
c/o Ensors Chartered Accountants, Victory House Vision Park, Chivers Way
Histon
United Kingdom
CB24 9ZR
+44 7711237599
fpinocci@missiontherapuetics.com

Additional identifiers

Clinical Trials Information System (CTIS)
2024-517310-15

Integrated Research Application System (IRAS)
1008552

Protocol serial number
MTX325-101

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

Primary study design
Interventional

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

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)
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)
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Completion date
17/09/2027

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

Total final enrolment
0

Key exclusion criteria
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Date of first enrolment
06/02/2024

Date of final enrolment
16/07/2027

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
Wales
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

IPD sharing plan summary
Not expected to be made available