

Deferred registration: HMR code: 25-008

Submission date 09/07/2026	Recruitment status Recruiting	☒ Prospectively registered ☐ Protocol
Registration date 15/07/2026	Overall study status Deferred	☐ Statistical analysis plan ☐ Results
Last Edited 15/07/2026	Condition category Other	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

This is a phase I trial in healthy volunteers only and qualifies for an automatic deferral. The full details will be added to the trial record on or before the deferral expiry date.

Contact information

Type(s)

Public, Scientific

Contact name

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Type(s)

Principal investigator

Contact name

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Contact details

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Additional identifiers

Integrated Research Application System (IRAS)
1012821

Sponsor Protocol Code
OT-003-P1-001

Study information

Scientific Title
Deferred registration: HMR code: 25-008
Full scientific title to be added on or before the deferral expiry date

Study objectives
This is a phase I trial in healthy volunteers only and qualifies for an automatic deferral. The full details will be added to the trial record on or before the deferral expiry date.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/12/2025, North East - York Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44(0) 207 104 8079; york.rec@hra.nhs.uk), ref: 25/NE/0163

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Phase I trial in healthy participants

Study type(s)**Health condition(s) or problem(s) studied**

Healthy volunteers

Interventions

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Intervention Type

Drug

Phase

Phase I

Drug/device/biological/vaccine name(s)

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Primary outcome(s)

1. [Outcome] measured using [measure] at [timepoint]. This is a phase I trial in healthy volunteers only and qualifies for an automatic deferral. The full details will be added to the trial record on or before the deferral expiry date.

Key secondary outcome(s)

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Completion date

23/09/2027

Eligibility**Key inclusion criteria**

Healthy human volunteer

Healthy volunteers allowed

Yes

Age group

Adult

Lower age limit

18 Years

Upper age limit

55 Years

Sex

All

Total final enrolment

0

Key exclusion criteria

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Date of first enrolment

21/07/2026

Date of final enrolment

31/05/2027

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Hammersmith Medicines Research

Hammersmith Medicines Research (HMR), Cumberland Avenue, Park Royal

London

England

NW10 7EW

Sponsor information

Organisation

OnTrack Therapeutics Limited (a wholly owned subsidiary of Pangea Botanica Ltd [trading as Pangea Bio])

Funder(s)

Funder type

Funder Name

Pangea Botanica Ltd [trading as Pangea Bio])

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available