ISRCTN69652929 https://doi.org/10.1186/ISRCTN69652929

Phase I Trial: 36540 (DF-PK-01)

Submission date 16/02/2026	**Recruitment status** Recruiting	[_] Prospectively registered [_] Protocol
Registration date 16/02/2026	**Overall study status** Deferred	[_] Statistical analysis plan [_] Results
Last Edited 16/06/2026	**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.

Contact information

Type(s)
Scientific, Public

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Additional identifiers

Integrated Research Application System (IRAS)
1012899

Study information

Scientific Title
Phase I Trial: 36540 (DF-PK-01)

Study objectives
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Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 18/12/2025, Wales Research Ethics Committee 2 (Health and Care Research Wales, Floor 4, Crown Building, Cathays Park, Cardiff, CF10 3NQ, United Kingdom; +44 (0)2922 941119; Wales.REC2@wales.nhs.uk), ref: 25/WA/0252

2. Approved 22/12/2025, MHRA (MHRA, 10 South Colonnade, Canary Wharf, London, E14 4PU, United Kingdom; +44 (0)20 3080 6000; info@mhra.gov.uk), ref: CTA 61689/0001/001-0001

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Crossover

Purpose
Device feasibility

Study type(s)

Health condition(s) or problem(s) studied

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Interventions
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Intervention Type
Drug/Device

Phase
Phase I

Drug/device/biological/vaccine name(s)
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Primary outcome(s)
1. [Outcome name] measured using [metric or method of measurement] at [timepoint(s)]

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Key secondary outcome(s)

Completion date
31/12/2026

Eligibility

Key inclusion criteria
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Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
20 Years

Upper age limit

65 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
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Date of first enrolment
09/01/2026

Date of final enrolment
01/12/2026

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Simbec-Orion Clinical Pharmacology (AKA Simbec Research Ltd)
Simbec-Orion Clinical Pharmacology, Merthyr Tydfil Industrial Park, Cardiff Road
Merthyr Tydfil
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CF48 4DR

Sponsor information

Organisation
DF Medical Ventures Limited

Funder(s)

Funder type

Funder Name
DF Medical Ventures Limited

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available