

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

Submission date 16/02/2026	Recruitment status Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/02/2026	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 16/02/2026	Condition category Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

Contact name

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Type(s)

Principal investigator

Contact name

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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

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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

19/06/2026

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

05/06/2026

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

Wales

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