

Phase 1 Trial: 36342 (DT-101/102)

Submission date 10/06/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 10/06/2025	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 10/06/2025	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)

Public, Scientific

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Type(s)

Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil Known

IRAS number

1010853

ClinicalTrials.gov number

Nil Known

Secondary identifying numbers

DT-101/102

Study information

Scientific Title

Phase 1 Trial: 36342 (DT-101/102)

Study objectives

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Ethics approval required

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Ethics approval(s)

1. Approved 16/04/2025, Wales Research Ethics Committee 2 (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 2922 941119; Wales.REC2@wales.nhs.uk), ref: 25.WA.0066

2. Approved 22/04/2025, MHRA (MHRA, 10 South Colonnade, Canary Wharf,, London, E14 4PU, United Kingdom; +44 (0) 20 3080 6000; info@mhra.gov.uk), ref: CTA 60755/0001/001-0001

Study design

Interventional randomized cross over open label study

Primary study design

Interventional

Secondary study design

Randomised cross over trial

Study setting(s)

Pharmaceutical testing facility, Other

Study type(s)

Other, Safety

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

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Interventions

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Intervention Type

Drug

Pharmaceutical study type(s)

Pharmacokinetic

Phase

Phase I

Drug/device/biological/vaccine name(s)

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Primary outcome measure

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Secondary outcome measures

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Overall study start date

19/02/2025

Completion date

17/06/2025

Eligibility**Key inclusion criteria**

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Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Upper age limit

55 Years

Sex

Both

Target number of participants

15

Total final enrolment

15

Key exclusion criteria

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Date of first enrolment

30/04/2025

Date of final enrolment

04/06/2025

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

United Kingdom

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Sponsor information

Organisation

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Sponsor type

Industry

Website

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Funder(s)

Funder type

Industry

Funder Name

Draig Therapeutics Ltd

Results and Publications

Publication and dissemination plan

Full trial details will be published up to 30 months after the end of the trial. Publication of some trial details is deferred because of the high commercial sensitivity of this phase I study and the negligible benefit to the public of phase I information. Results will be posted on or after the date of publication of full trial details.

Intention to publish date

17/12/2027

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

Data sharing statement to be made available at a later date