ISRCTN15553015 https://doi.org/10.1186/ISRCTN15553015

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

Submission date 10/06/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 10/06/2025	**Overall study status** Deferred	
Last Edited 10/06/2025	**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

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Public, Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
1010853

Protocol serial number
DT-101/102

Study information

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

Study objectives
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Ethics approval required
Ethics approval required

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

Study type(s)
Other, 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
17/06/2025

Eligibility

Key inclusion criteria
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Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
55 years

Sex
All

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
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Sponsor information

Organisation
Draig Therapeutics Ltd

Funder(s)

Funder type
Industry

Funder Name
Draig Therapeutics Ltd

Results and Publications

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