ISRCTN50947231 https://doi.org/10.1186/ISRCTN50947231

Phase 1 Trial: CSD241701

Submission date 17/11/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 18/11/2024	**Overall study status** Deferred	[_] Statistical analysis plan [_] Results
Last Edited 18/11/2024	**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.

Study website
Not applicable

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
344408

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CSD241701

Study information

Scientific Title
Phase 1 Trial: CSD241701
The full scientific title will be published within 30 months after the end of the trial

Study objectives
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Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 18/07/2024, Office for Research and Ethics Committee Northern Ireland (Business Services Organisation Unit 4, Lissue Industrial Estate West, Rathdown Walk, Moira Road, Lisburn, Belfast, BT28 2RF, United Kingdom; +44 (0)28 9536 1400; info.orecni@hscni.net), ref: 24-NI-0077

Study design
Interventional single-centre randomized cross-over trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Safety, Efficacy

Participant information sheet
Not applicable

Health condition(s) or problem(s) studied
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Interventions
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.

Intervention Type
Other

Primary outcome measure
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.

Secondary outcome measures
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.

Overall study start date
01/05/2024

Completion date
26/08/2024

Eligibility

Key inclusion criteria
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Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
21 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
42

Key exclusion criteria
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Date of first enrolment
19/07/2024

Date of final enrolment
19/08/2024

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
Celerion Belfast
22-24 Lisburn Rd, Belfast
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Sponsor information

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Reynolds American (United States)

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Sponsor type
Industry

Website
https://www.reynoldsamerican.com/

ROR
https://ror.org/05qcjd272

Funder(s)

Funder type
Industry

Funder Name
Reynolds American Inc. Services

Results and Publications

Publication and dissemination plan
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.

Intention to publish date
31/12/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the protection of commercially confidential information

IPD sharing plan summary

Not expected to be made available