

Phase 1 Trial: CSD241701

Submission date 17/11/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 18/11/2024	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 18/11/2024	Condition category Other	<input type="checkbox"/> Individual participant data <input 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.

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Additional identifiers**Clinical Trials Information System (CTIS)**

Nil known

Integrated Research Application System (IRAS)

344408

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

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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

Study type(s)

Safety, Efficacy

Health condition(s) or problem(s) studied

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Interventions

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Intervention Type

Other

Primary outcome(s)

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Key secondary outcome(s)

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Completion date

26/08/2024

Eligibility**Key inclusion criteria**

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Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

21 years

Upper age limit

60 years

Sex

All

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**

United Kingdom

Northern Ireland

Study participating centre**Celerion Belfast**

22-24 Lisburn Rd, Belfast

Belfast

United Kingdom

BT9 6AD

Sponsor information**Organisation**

Reynolds American (United States)

ROR

<https://ror.org/05qcjd272>

Funder(s)**Funder type**

Industry

Funder Name

Reynolds American Inc. Services

Results and Publications**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