

# Phase 1 Trial: CSD241701

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

**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**

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

**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