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 [ ] 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

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

Primary study design
Interventional

Study design
Interventional single-centre randomized cross-over trial

Study type(s)
Safety, Efficacy

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(s)
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Key secondary 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.

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