

Phase II study. The Newcastle upon Tyne Hospitals NHS Foundation Trust code: 09422

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| Submission date 27/04/2022 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 28/04/2022 | Overall study status Deferred | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 05/05/2022 | Condition category Not Specified | <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 when the results are published, which will be within 30 months after the trial has ended.

Contact information

Type(s)

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Additional identifiers

Clinical Trials Information System (CTIS)
2020-004958-30

Integrated Research Application System (IRAS)
1004317

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 1004317; The Newcastle upon Tyne Hospitals NHS Foundation Trust code: 09422; CPMS 51903

Study information

Scientific Title
Phase II study. The Newcastle upon Tyne Hospitals NHS Foundation Trust code: 09422
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Study objectives
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Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 08/03/2022, London - Hampstead Research Ethics Committee (Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN, UK; +44 207 104 8345; hampstead.rec@hra.nhs.uk), ref: 22/LO/0115
2. Approved 09/03/2022, MHRA (10 South Colonnade, Canary Wharf, London E14 4PU; +44 20 3080 6000; info@mhra.gov.uk), ref: CTA 17136/0298/001-0001

The HRA has approved deferral of publication of trial details.

Study design
Single centre interventional double-blind phase II trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

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Interventions

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Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

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Primary outcome(s)

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Key secondary outcome(s)

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Completion date

31/08/2023

Eligibility

Key inclusion criteria

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Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

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Date of first enrolment

01/06/2022

Date of final enrolment

31/01/2023

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

The Newcastle upon Tyne Hospitals NHS Foundation Trust

Freeman Hospital

Freeman Road

High Heaton

Newcastle upon Tyne

United Kingdom

NE7 7DN

Sponsor information**Organisation**

Newcastle upon Tyne Hospitals NHS Foundation Trust

ROR

<https://ror.org/05p40t847>

Funder(s)

Funder type

Industry

Funder Name

Intercept Pharmaceuticals

Alternative Name(s)

Intercept, Intercept Pharma, Intercept Pharmaceuticals, Inc., Intercept Pharmaceuticals Inc

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Results and Publications

Individual participant data (IPD) sharing plan

Data sharing statement to be made available at a later date .

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| HRA research summary | | | 28/06/2023 | No | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |