

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

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)

Principal Investigator

Contact name

Prof David Jones

Contact details

Institute of Cellular Medicine
4th Floor William Leech Building
Framlington Place
Newcastle upon Tyne
United Kingdom
NE2 4HH
+44 1912087572
david.jones@ncl.ac.uk

Type(s)

Public

Contact name

Mrs Irena Bibby

Contact details

Newcastle Clinical Trials Unit
1-4 Claremont Terrace

Newcastle University
Newcastle upon Tyne
United Kingdom
NE2 4AE
+44 1912082526
oacstrials@newcastle.ac.uk

Additional identifiers

EudraCT/CTIS number
2020-004958-30

IRAS number
1004317

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

No participant information sheet available

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 measure

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Secondary outcome measures

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Overall study start date

17/01/2022

Completion date

31/08/2023

Eligibility

Key inclusion criteria

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Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

25

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

England

United Kingdom

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

Sponsor details

Level 1 Regent Point

Newcastle upon Tyne

England

United Kingdom

NE3 3HD

+44 1912824461

tnu-tr.sponsormanagement@nhs.net

Sponsor type

Hospital/treatment centre

Website

<http://www.newcastle-hospitals.org.uk/>

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

Publication and dissemination plan

Trial information and summary results will be published up to 30 months after the end of the trial. Publication of some trial details is deferred because of the high commercial sensitivity of this phase II study and the negligible benefit to the public of phase II information.

Intention to publish date

28/02/2026

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