

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

<b>Submission date</b> 27/04/2022	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 28/04/2022	<b>Overall study status</b> Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 05/05/2022	<b>Condition category</b> 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

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### Type(s)

Public

### Contact name

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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?
<a href="#">HRA research summary</a>			28/06/2023	No	No