ISRCTN98936300 https://doi.org/10.1186/ISRCTN98936300

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

Submission date 27/04/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 28/04/2022	**Overall study status** Deferred	
Last Edited 05/05/2022	**Condition category** Not Specified	

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

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

Integrated Research Application System (IRAS)
1004317

Central Portfolio Management System (CPMS)
51903

Protocol serial number
The Newcastle upon Tyne Hospitals NHS Foundation Trust code: 09422

Study information

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

Study objectives
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.

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.

Primary study design
Interventional

Study design

Single centre interventional double-blind phase II trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
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.

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 when the results are published, which will be within 30 months after the trial has ended.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(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 when the results are published, which will be within 30 months after the trial has ended.

Primary 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 when the results are published, which will be within 30 months after the trial has ended.

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 when the results are published, which will be within 30 months after the trial has ended.

Completion date
31/08/2023

Eligibility

Key inclusion criteria
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.

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Sex
All

Key exclusion criteria
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.

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