ISRCTN45338135 https://doi.org/10.1186/ISRCTN45338135

Phase I trial: PXL 272092

Submission date 19/05/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 20/05/2022	**Overall study status** Deferred	[_] Statistical analysis plan [_] Results
Last Edited 20/05/2022	**Condition category** Other	[_] Individual participant data [_] Record updated in last year

Plain English Summary
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

EudraCT/CTIS number
Nil known

IRAS number
1005630

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 1005630, PXL 272092

Study information

Scientific Title
Phase I trial: PXL 272092

Study hypothesis
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Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 05/05/2022, London-Brent REC (80 London Road, Skipton House, London, SE1 6LH, UK; +44(0)20 7104 8137; brent.rec@hra.nhs.uk), ref: 22/LO/0315
2. Approved 05/05/2022, MHRA (10 South Colonnade, Canary Wharf, London, E14 4PU, UK; +44 (0) 20 3080 6000; info@mhra.gov.uk), ref: CTA 46323/0005/001-0001

Study design
Pharmacokinetic pharmacodynamic safety and tolerability study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
No participant information sheet available

Condition
Healthy volunteers

Interventions
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Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
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Primary outcome measure
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Secondary outcome measures

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.

Overall study start date
19/04/2022

Overall study end date
30/09/2022

Eligibility

Participant inclusion criteria
Healthy human volunteer

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Male

Target number of participants
8

Participant exclusion criteria
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Recruitment start date
29/06/2022

Recruitment end date
30/09/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Parexel Early Phase Clinical Unit
Level 7, Northwick Park Hospital
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Sponsor information

Organisation
Hansa Biopharma (Sweden)

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Sponsor type
Industry

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https://ror.org/001r0mk78

Funder(s)

Funder type
Industry

Funder Name
Hansa Biopharma AB

Results and Publications

Publication and dissemination plan

Full trial details 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 I study and the negligible benefit to the public of phase I information. Results will be posted on or after the date of publication of full trial details.

Intention to publish date
31/03/2025

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study are not expected to be made available because of their high commercial sensitivity and the negligible benefit to the public of publication of results of non-therapeutic clinical trials.

IPD sharing plan summary
Not expected to be made available