

# A phase 1 trial evaluating the absorption, safety and tolerability of imlifidase after a single dose in healthy Japanese men

<b>Submission date</b> 19/05/2022	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 20/05/2022	<b>Overall study status</b> Deferred	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 27/05/2025	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Principal investigator

### Contact name

Dr David Steel

### Contact details

Parexel Early Phase Clinical Unit  
Level 7, Northwick Park Hospital  
Watford Road  
Harrow  
London  
United Kingdom  
HA1 3UJ  
+44 (0)808 134 6555  
drugtrial@parexel.com

### Type(s)

Scientific

### Contact name

Dr David Steel

### Contact details

Parexel Early Phase Clinical Unit  
Level 7, Northwick Park Hospital  
Watford Road  
Harrow  
London  
United Kingdom  
HA1 3UJ  
+44 (0)808 134 6555  
drugtrial@parexel.com

**Type(s)**

Public

**Contact name**

Dr David Steel

**Contact details**

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+44 (0)808 134 6555  
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## Additional identifiers

**Clinical Trials Information System (CTIS)**

Nil known

**Integrated Research Application System (IRAS)**

1005630

**Protocol serial number**

IRAS 1005630, PXL 272092

## Study information

**Scientific Title**

A phase 1 trial evaluating the pharmacokinetics, pharmacodynamics, safety, and tolerability of imlifidase after administration of a single intravenous dose in healthy Japanese men

**Study objectives**

PK/PD in healthy Japanese volunteers

**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

## Study type(s)

Other

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

Healthy volunteers

## Interventions

All subjects received an intravenous dose of 0.25 mg/kg imlifidase on Day 1, administered over 15 minutes. Follow up for 14 days.

## Intervention Type

Drug

## Phase

Phase I

## Drug/device/biological/vaccine name(s)

Imlifidase

## Primary outcome(s)

PK was measured as concentration of imlifidase in serum from pre-dose until Day 14

## Key secondary outcome(s)

1. Safety was assessed as adverse events (AEs) from obtaining the informed consent throughout the study. An AE is any untoward medical occurrence in a subject participating in the clinical trial. An AE could be any unfavourable and unintended sign, symptom or disease temporally associated with the treatment, whether or not considered related to the study drug
2. PD was assessed as concentration of IgG in serum throughout the study

## Completion date

30/09/2022

## Eligibility

### Key inclusion criteria

1. Healthy man
2. Between 20 and 60 years old
3. Both parents and all 4 grandparents were ethnically Japanese

**Participant type(s)**

Healthy volunteer

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Male

**Key exclusion criteria**

1. Previous participation in this study
2. Present participation in another clinical trial, or use of any investigational drug or therapy, taking into account participation in a medical device study, within 90 days or 5 half-lives, whichever is longer, prior to administration of IMP
3. Presence or history of any clinically significant disease or disorder which, in the opinion of the Investigator, may either put the subject at risk because of participation in the study, or influence the results or the subject's ability to participate in the study

**Date of first enrolment**

29/06/2022

**Date of final enrolment**

30/09/2022

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre****Parexel Early Phase Clinical Unit**

Level 7, Northwick Park Hospital

Watford Road

Harrow

London

United Kingdom

HA1 3UJ

**Sponsor information**

## Organisation

Hansa Biopharma (Sweden)

## ROR

<https://ror.org/001r0mk78>

## Funder(s)

### Funder type

Industry

### Funder Name

Hansa Biopharma AB

## Results and Publications

### 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

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Basic results</a>		23/05/2025	23/05/2025	No	No