

Phase I Study (PHU-001)

Submission date 23/01/2026	Recruitment status Not yet recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/01/2026	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 28/01/2026	Condition category Other	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

The sponsor has confirmed that the trial meets the criteria for 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.

Contact information

Type(s)

Principal investigator, Public, Scientific

Contact name

Dr Guglielmo Niccolò Piozzi

Contact details

Queen Alexandra Hospital, Portsmouth Hospitals University NHS Trust, Southwick Hill Road,
Cosham
Portsmouth
United Kingdom
PO6 3LY
+44 2392286000 (Ext. 5421)
guglielmo.piozzi@nhs.net

Additional identifiers

Integrated Research Application System (IRAS)
346045

Study information

Scientific Title

Phase I Study (PHU-001)

The full scientific title will be published within 30 months after the end of the trial.

Study objectives

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 09/01/2026, Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (NHSBT Newcastle Blood Donor Centre Holland Drive, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 207 104 8081; bradfordleeds.rec@hra.nhs.uk), ref: 24/YH/0255

Primary study design

Interventional

Allocation

N/A: single arm study

Masking

Open (masking not used)

Control

Historical

Assignment

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Purpose

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Study type(s)

Health condition(s) or problem(s) studied

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Interventions

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Intervention Type

Device

Phase

Phase I

Drug/device/biological/vaccine name(s)

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Primary outcome(s)

1. - measured using - at -

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Key secondary outcome(s))

Completion date

30/04/2027

Eligibility

Key inclusion criteria

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Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

90 years

Sex

All

Total final enrolment

0

Key exclusion criteria

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Date of first enrolment

20/03/2026

Date of final enrolment

31/03/2027

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Portsmouth Hospitals University NHS Trust

Queen Alexandra Hospital

Southwick Hill Road

Cosham

Portsmouth

England

PO6 3LY

Sponsor information

Organisation

Cornerstone Robotics Limited

Funder(s)

Funder type

Funder Name

Cornerstone Robotics Limited

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available