

# Phase I Study (PHU-001)

<b>Submission date</b> 23/01/2026	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 28/01/2026	<b>Overall study status</b> Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 18/02/2026	<b>Condition category</b> 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

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## Additional identifiers

### Integrated Research Application System (IRAS)

346045

### Central Portfolio Management System (CPMS)

65386

## 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