ISRCTN34438231 https://doi.org/10.1186/ISRCTN34438231

Phase I Study (PHU-001)

Submission date 23/01/2026	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 28/01/2026	**Overall study status** Deferred	
Last Edited 18/02/2026	**Condition category** Other	

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

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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
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.

Purpose
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.

Study type(s)

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

Interventions
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.

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