ISRCTN57194862 https://doi.org/10.1186/ISRCTN57194862

Handheld robot for minimally invasive neurosurgery

Submission date 29/08/2025	**Recruitment status** Not yet recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 04/09/2025	**Overall study status** Ongoing	
Last Edited 01/09/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Pituitary tumours are commonly treated with keyhole surgery through the nose, but the narrow corridor can limit the surgeon's dexterity and make complete, safe tumour removal difficult. The Panda Surgical Handheld System is a small, handheld robotic tool designed to improve precision in these tight spaces. This first-in-human study will evaluate whether using the Panda system during standard pituitary surgery is feasible and safe.

Who can participate?
Adults (aged 18+ years) with a pituitary adenoma on MRI who have been assessed by the pituitary multidisciplinary team and their neurosurgeon as suitable for endoscopic transsphenoidal surgery

What does the study involve?
Care follows the usual NHS pathway for endoscopic transsphenoidal surgery. During the operation, the surgeon may use the Panda handheld device alongside standard instruments to assist with precise tumour removal under endoscopic vision. No additional hospital visits beyond routine care are planned; outcomes are assessed up to 6 months after surgery.

What are the possible benefits and risks of participating?
Potential benefits include more precise tumour removal and safer manoeuvring around delicate structures; however, personal benefit cannot be guaranteed in this early study. Risks are expected to be similar to standard surgery because the device is used as an adjunct.

Where is the study run from?
The National Hospital for Neurology and Neurosurgery (NHNN), London - a high-volume UK pituitary centre

When is the study starting and how long is it expected to run for?
October 2025

Who is funding the study?
1. National Institute for Health and Care Research (NIHR) (UK)
2. Panda Surgical Ltd (UK)

Who is the main contact?
Dr John Hanrahan, j.hanrahan@ucl.ac.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Mr John Hanrahan

ORCID ID
https://orcid.org/0000-0003-4584-2298

Contact details
National Hospital for Neurology and Neurosurgery
London
United Kingdom
WC1N 3BG
+44 (0)7912220155
j.hanrahan@ucl.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
360322

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
A handheld robot for minimally invasive neurosurgery – a single-centre, open-label early feasibility and safety study (IDEAL Stage 1) in patients undergoing surgery for pituitary adenoma

Acronym
HARMONY

Study objectives
To determine the technical feasibility and clinical safety of the Panda Surgical Handheld System in patients undergoing surgery for pituitary adenoma

Ethics approval required
Ethics approval required

Ethics approval(s)
Not yet submitted 25/06/2025, Ethics committee name not provided (Address not provided, City not provided, Zip/postal code not provided; Telephone number not provided; Email not provided), ref: Reference number not provided

Study design
Open-label non-randomized single-arm single-centre interventional study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Pituitary adenoma

Interventions
Care follows the usual NHS pathway for endoscopic transsphenoidal surgery. During the operation, the surgeon may use the Panda handheld device alongside standard instruments to assist with precise tumour removal under endoscopic vision. No additional hospital visits beyond routine care are planned; outcomes are assessed up to 6 months after surgery.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Phase I

Drug/device/biological/vaccine name(s)
Panda Surgical Handheld System

Primary outcome measure

1. Feasibility, defined as successful intraoperative use of the Panda Surgical Handheld System during tumour removal and/or closure, as recorded in the surgical operation note and confirmed by independent blinded video review. Timepoint: Intraoperative (day of surgery).
2. Safety, incidence of device-related adverse events and device deficiencies, recorded via case report forms and adverse event reporting, adjudicated by independent video review. Timepoint: From intraoperative period through 6-month follow-up.

Secondary outcome measures

1. Intraoperative arterial injury, recorded in operation note and confirmed on video review. Timepoint: Intraoperative.
2. Post-operative cerebrospinal fluid (CSF) leak, recorded in case notes and confirmed radiologically/clinically. Timepoint: During inpatient stay and up to 6 months post-surgery.
3. Infection (including meningitis), recorded from clinical notes and microbiology results. Timepoint: Inpatient stay up to 6 months post-surgery.
4. Extent of resection measured using post-operative MRI with contrast. Timepoint: Approximately 4 months post-surgery.
5. Need for subsequent intervention for complication, documented from case notes. Timepoint: Within 30 days post-surgery.
6. Mortality: survival status recorded from hospital records. Timepoint: At 6 months post-surgery.

Endocrine outcomes:
7. New hypopituitarism, assessed by pituitary hormone panel (cortisol, prolactin, FT4, TSH, IGF-1, GH, LH, FSH, testosterone). Timepoint: Post-op inpatient stay, endocrine clinic review, and 6 months.
8. Recovery of pituitary function, assessed by pituitary hormone panel (cortisol, prolactin, FT4, TSH, IGF-1, GH, LH, FSH, testosterone). Timepoint: At 6 months.
9. Remission (functioning adenomas) assessed by biochemical hormone markers. Timepoint: At 6 months.
10. Post-operative dysnatremia assessed by serum sodium monitoring. Timepoint: Inpatient stay and up to 6 months.
11. Sexual/reproductive health outcomes assessed using clinical history and endocrine profile. Timepoint: At 6 months.

Ophthalmic outcomes:
12. Visual acuity measured using Snellen chart or equivalent. Timepoint: Pre-op, inpatient stay, 6 months.
13. Visual fields measured by formal perimetry. Timepoint: Pre-op, inpatient stay, 6 months.

Nasal outcomes:
14. Sense of smell/taste assessed by patient self-report and clinical review. Timepoint: Inpatient stay and 6 months.

Quality of life outcomes:
15. General health status measured using SF-36 questionnaire. Timepoint: Pre-operatively (twice, two weeks apart), and at 3 and 6 months post-op.
16. Pituitary-specific quality of life measured using Pituitary Outcome Score. Timepoint: Pre-operatively, 3 and 6 months post-op.

Other outcomes:
17. Readmission recorded from hospital records. Timepoint: Within 30 days post-surgery.

Long-term disease control:
18. Re-operation, need for radiotherapy, or need for additional medical therapy, recorded in patient records. Timepoint: Up to 6 months.
19. Recurrent disease assessed using biochemical hormone profile or MRI imaging. Timepoint: At 6 months.

Resource use/cost:
20. Intraoperative resource use: operating time and equipment used, recorded in theatre log. Timepoint: Intraoperative.
21. Patient-level costs collected via hospital records (length of stay, re-intervention). Timepoint: Inpatient stay and up to 6 months.

Overall study start date
25/06/2025

Completion date
25/12/2026

Eligibility

Key inclusion criteria
1. Adult patient ≥18 years
2. Suspected pituitary adenoma defined on a dedicated contrast-enhanced pituitary MRI scan
3. Capacity to consent for research study
4. Able to meet the proposed primary study schedule including face-to-face clinic reviews

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
6

Key exclusion criteria
1. Paediatric patients
2. Patients without capacity to consent for study
3. Patients undergoing transcranial surgery
4. Previous transsphenoidal surgery in previous 12 months
5. Radiological evidence of an alternative diagnosis (pituitary hypophysitis)
6. Patients with contraindications to undergo magnetic resonance imaging

7. Patients with contraindications to intravenous gadolinium contrast for imaging
8. Unmanaged chronic infection
9. Uncontrolled chronic health condition precluding safe anaesthesia

Date of first enrolment
30/10/2025

Date of final enrolment
30/03/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
National Hospital for Neurology & Neurosurgery
Queen Square
London
United Kingdom
WC1N 3BG

Sponsor information

Organisation
University College London

Sponsor details
Joint Research Office
Maple House
149 Tottenham Court Road
London
England
United Kingdom
W1T 7BN
+44 (0)20 3447 5369
uclh.jro-communications@nhs.net

Sponsor type
Research organisation

Website
http://www.ucl.ac.uk/

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Industry

Funder Name
Panda Surgical

Funder Name
NIHR i4i

Results and Publications

Publication and dissemination plan
Planned publication in peer reviewed journal.

Intention to publish date
20/02/2026

Individual participant data (IPD) sharing plan
Datasets generated will be available upon reasonable request from Mr John Hannahan (j.hanrahan@ucl.ac.uk).•
The type of data that will be shared: De-identified participant-level data (baseline demographics, surgical outcomes, adverse events, endocrine/ophthalmic/nasal outcomes, and quality of life questionnaires), along with the study protocol and statistical analysis plan.
Data will be available from study completion (expected 2026) for a minimum of 5 years. Consent for data sharing will be included in the consent form. All data will be deidentified and anonymised.

IPD sharing plan summary
Available on request