ISRCTN18159384 https://doi.org/10.1186/ISRCTN18159384

A study of the use of robotic surgery for outpatient surgery to determine the effect on recovery

Submission date
26/07/2023

Recruitment status
Recruiting

Registration date
11/09/2023

Overall study status
Ongoing

Last Edited
19/07/2024

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
This study is part of a research project to investigate the role of a robotic outpatient surgery program in the NHS. Outpatient surgery means that the patient is able to go home within 24 hours after the surgery, usually without the need to stay in hospital overnight. Robotic surgery means that the operation is done by a human surgeon using an advanced tool (the robotic platform) to perform the surgery through small cuts in the body. This robot is not autonomous, meaning that at no point is a robot performing the operation itself, a human surgeon will be controlling the robot during the entire operation.

Who can participate?
Patients aged 18 years or above within Portsmouth Queen Alexandra Hospital who are scheduled for a robotic procedure.

What does the study involve?
The researchers want to study clinical outcomes, such as how quickly participants are able to leave the hospital after surgery, economic outcomes, such as how much robotic outpatient surgery costs to the NHS, and efficiency outcomes, such as whether patients are able to be operated on sooner.

What are the possible benefits and risks of participating?
Robotic surgery has been around since the early 2000s and is already being used successfully for these types of operations across the world. However, the benefits and costs of robotic surgery have not yet been fully examined. That is why this study has been set up to find out the impact that the robotic platform has on outpatient surgery within the NHS.

Where is the study run from?
Portsmouth Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
July 2023 to September 2026

Who is funding the study?
Intuitive Surgical Limited (UK)

Who is the main contact?
1. Ian Gedge, ian.gedge@porthosp.nhs.uk
2. Prof. Jim Khan, jim.khan@porthosp.nhs.uk

Contact information

Type(s)
Public

Contact name
Mr Ian Gedge

Contact details
1st Floor Lancaster House
Queen Alexandra Hospital
Portsmouth
United Kingdom
PO6 3LY
+44 (0)2392286000
ian.gedge@porthosp.nhs.uk

Type(s)
Scientific

Contact name
Prof Jim Khan

ORCID ID
https://orcid.org/0000-0002-3031-4495

Contact details
Queen Alexandra Hospital
Cosham
United Kingdom
PO6 3LY
+44 (0)23292 286000
jim.khan@porthosp.nhs.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
327536

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number
CPMS 56913, IRAS 327536

Study information

Scientific Title
Multispecialty robotic outpatient surgery program for improved length of stay and recovery

Acronym
MAYFLY

Study objectives
A multispecialty robotic outpatient surgery program will improve length of stay and recovery time for patients in a national healthcare setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/07/2023, West of Scotland REC 5 (West of Scotland Research Ethics Service, Ground Floor Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, UK; +44 (0)141 314 0213; WoSREC5@ggc.scot.nhs.uk), ref: 23/WS/0100

Study design
Observational cohort study

Primary study design
Observational

Study type(s)
Treatment

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

Interventions
A prospective, single-centre, observational study assessing the implementation of a multispecialty robotic outpatient program in the national healthcare setting.

The study is looking to recruit all patients treated in the robotic outpatient unit, which we estimate will lead to 600-1200 inclusions per year. The researchers will not be seeking to randomise these patients.

Participation in the trial will not alter surgical care or treatment in any way, shape, or form. There is no direct benefit and no additional risk for patients participating in this research.

Eligible robotic outpatients will be recruited. A patient is eligible when he/she meets all the inclusion criteria and none of the exclusion criteria of this study. All eligible patients will be logged in a screening log to ensure no patient selection will occur.

After the identification of possible eligible participants, the patient is correctly informed about the trial and after an acceptable period of consideration, voluntary informed consent will be asked. If a person is willing to participate, the informed consent form will be signed. Only subjects who have signed the study's informed consent will be included in the study. The participants have the right to withdraw at any time without reason or penalty.

The total study duration will be approximately 3 years. Study follow-up will be 12 months after the date of surgery. Patients will be asked to fill in Quality of Life and Quality of Recovery questionnaires before surgery, and at 2, 7, 30, and 365 days after surgery.

The Baseline visit
After informed consent is obtained, pre-operative baseline information will be collected. At this moment in time the participant will be asked to complete the aforementioned questionnaires. Patients have a standard of care preoperative clinical visit, and information will be collected from the medical records.

The Operative Procedure visit
During the operation routinely recorded parameters will be collected. These include how long the operation takes, system and instrument use, conversion to an open surgery, and any complications during the surgery.

The Post-Operative Course
Following surgery, patients will be taken to the postoperative recovery unit as per standard clinical care. Patients will receive standard post-operative care as per clinical pathways, with all treatment decisions made as per clinician expertise.

Follow-up visits
2 days (-12 to +24 hours)
At 2 days postoperatively, the patient will receive two questionnaire surveys to fill out (digitally or by mail).

7 days (-1 to +3 days)
At 7 days postoperatively, the patient will receive one questionnaire surveys to fill out (digitally or by mail). Patient records will be checked to identify any readmissions, reinterventions, and SAEs.

30 days (+- 7 days)
At 30 days postoperatively, the patient will receive two questionnaire surveys to fill out (digitally or by mail). The patient will be contacted for a telephone follow-up call, which is estimated to take around 5 minutes. A member of the research team will collect postoperative follow-up data from the patients' medical notes.

90 days (+/- 14 days)
A member of the research team will collect postoperative follow-up data from the patients' medical notes.

365 days (+/- 14 days)
At 365 days postoperatively, the patient will receive one questionnaire survey to fill out (digitally or by mail), after which the End of Study form will be completed.

The trial requires one additional follow-up phone call at 30 days and does not require any other additional investigations or patient contact throughout its duration.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Quality of life measured using EQ-5D and QoR-15 questionnaires at baseline and postoperative
2. Cost-effectiveness measured by comparing costs per procedure between laparoscopic and robotic outpatient surgeries through anonymized, routinely collected Trust level metrics at 6 monthly intervals for 3 years
3. Operational efficiency measured by comparing number of procedures done between laparoscopic and robotic outpatient units per list, month, and year through anonymized, routinely collected Trust level metrics in the first, second, and third year of the program
4. Peri-operative outcomes measured by comparing anonymized, routinely collected Trust level metrics for robotic and laparoscopic outpatients, including operative time (defined as time between first incision and last suture), anaesthetic time (defined as time between commencement and cessation of anaesthetic regimen), and theatre time (defined as time between wheeling patient in and out of the theatre) in the first, second, and third year of the program

Key secondary outcome(s))
1. Need for and benefits of additional endoscope sterilizing capacity throughout the robotic outpatient surgery program measured by comparing the amount of endoscopes sterilized with the maximum capacity of the sterilizing unit (defined as fraction of maximum potential) in the first, second, and third year of the program
2. Health-associated outcome benefits achieved throughout the robotic outpatient surgery program measured by comparing QALYs stratified per procedure between the robotic outpatients in the first, second, and third year of the program
3. Patient clinical outcomes throughout the robotic outpatient surgery program measured by comparing postoperative follow-up data (including complication rates, return to work, and readmissions/reinterventions) stratified per procedure between the robotic outpatients in the first, second, and third year of the program
4. Safe delivery of the robotic outpatient surgery program measured by analysing postoperative complications, morbidity, and mortality, and comparing to historical data and existing literature at 6 monthly intervals for 3 years
5. Impact of the robotic outpatient surgery program to robotic training for surgical trainees measured by comparing postoperative follow-up data stratified per procedure between the robotic outpatients procedures operated (in part) by a surgical trainee in the first, second, and third year of the program
6. Benefits of the robotic outpatient surgery program to robotic training for surgical trainees measured by analysing the number of robotic outpatients procedures operated (in part) by a surgical trainee throughout the program
7. Impact of the robotic outpatient surgery program to the main hospital elective program measured by comparing the total number of robotic procedures performed per specialty through anonymized, routinely collected Trust level metrics at 6 monthly intervals for 3 years

8. Impact of the robotic outpatient surgery program to the number of benign procedures performed measured by comparing the number of benign robotic procedures performed per specialty through anonymized, routinely collected Trust level metrics at 6 monthly intervals for 3 years
8. Impact of the robotic outpatient surgery program to the number of intraoperative staff members required per procedure measured by comparing staffing configurations stratified per procedure between the robotic outpatient operative lists in the first, second, and third year of the program

Completion date
30/09/2026

Eligibility

Key inclusion criteria
1. All patients treated at Portsmouth Hospitals University NHS Trust who undergo either a robotic outpatient procedure (defined as an anticipated post-procedure discharge time less than 24 hours) or a planned elective surgical inpatient procedure that is anticipated to be discharged within 24 hours.
2. Patients aged 18 years or above.
3. Must be willing and able to comply with study requirements.
4. Must indicate their understanding of the study and willingness to participate by signing an appropriate informed consent form.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Patients that have multiple resections planned in the same procedure.
2. Mental incapacity to understand or consent to study procedures.
3. Anticipated difficulty for patient to comply with protocol requirements.
4. Unable to comply with the follow up schedule.
5. Patients participating in additional research studies, which may impact the outcomes of this study.
6. Pregnant or breastfeeding patients.

Date of first enrolment
01/09/2023

Date of final enrolment
30/06/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Queen Alexandras Hospital
Southwick Hill Road
Cosham
Portsmouth
United Kingdom
PO6 3LY

Sponsor information

Organisation
Portsmouth Hospitals NHS Trust

ROR
https://ror.org/009fk3b63

Funder(s)

Funder type
Industry

Funder Name
Intuitive Surgical Limited

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.1	01/07/2023	04/08/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes