

Real-world evaluation of robot-assisted surgical services

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| Submission date 07/07/2022 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 10/10/2022 | Overall study status Ongoing | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 01/08/2025 | Condition category Surgery | <input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Background and study aims

This study aims to work out if robot-assisted surgery (RAS), a relatively new development, should be routinely available in the NHS and also assess any barriers to its implementation. Over the next 20 years, surgery performed with the help of a robot is expected to increase rapidly around the world, especially for cancer conditions. Previous research shows that when RAS has been introduced in some clinical areas, like urology, it can help surgeons be more precise and can reduce a patient's hospital stay. Using RAS may also speed up training for surgeons to enable them to become experts more quickly. However, RAS has not been tested in all clinical areas and is very expensive with each robot costing over £ 1 million). Also, when RAS is introduced into hospitals it requires special consideration as the set-up can be disruptive. It is not yet clear whether the benefits to patients or the health system of doing surgery this way is worth the cost and the disruption. This study aims to answer that question and provide guidelines for the best way of doing it if robotic surgery is shown to be useful.

We have designed the research to be able to measure the impact of RAS as it is introduced in the UK and scaled up in other hospitals currently performing robotic surgery but planning to expand services. It will study the effects of RAS as it is rolled out at 16 different sites in a planned way. We will measure what happens to patients who get RAS as part of the service and compare their outcomes (e.g., complications, recovery time) to conventional surgery. We will also track how introducing RAS impacts on the staff and the surgeons, and how it affects wider care in hospitals across the country.

This study aims to undertake a real-world, large-scale evaluation of the introduction and scale-up of RAS services evaluating its impact on NHS service delivery, clinical effectiveness, budget and cost-effectiveness.

Who can participate?

Any patient undergoing the specified surgical procedure at a participating hospital site

What does the study involve?

The study involves patients completing a questionnaire before and after surgery to evaluate

their experience of the procedure. We will also interview and survey staff involved with REINFORCE at sites, and calculate the total cost to the NHS (e.g., labour, consumables and other items of surgical equipment).

What are the possible benefits and risks of participating?

There is no direct benefit to participants, but the results of the study are likely to benefit future NHS patients undergoing surgery. Outside of the usual risks associated with surgery and anaesthetic, there are no anticipated risks or disadvantages to participating in the REINFORCE study.

Where is the study run from?

Surgical Intervention Trials Unit (SITU), University of Oxford and Centre for Healthcare Randomised Trials (CHaRT), University of Aberdeen (United Kingdom)

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

January 2022 to August 2025

Who is funding the study?

NIHR Health and Social Care Delivery Research (NIHR HSDR) (United Kingdom)

Who is the main contact?

REINFORCE@ndorms.ox.ac.uk

Study website

<https://w3.abdn.ac.uk/hsru/REINFORCE/>

Contact information

Type(s)

Public

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

311223

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CPMS 53026, IRAS 311223

Study information

Scientific Title

A real-world, in-situ, evaluation of the introduction and scale-up of robot-assisted surgical services in the NHS: Evaluating its impact on clinical and service delivery, effectiveness and cost (the REINFORCE study)

Acronym

REINFORCE

Study objectives

This study aims to undertake a real-world, large-scale evaluation of the introduction and scale-up of Robot-Assisted Surgery (RAS) services evaluating its impact on NHS service delivery, clinical effectiveness, budget and cost-effectiveness.

Ethics approval required

Old ethics approval format

Ethics approval(s)

This is an observational study of healthcare professionals. The Sponsor, University of Oxford, reviewed the study as a Service Evaluation project and indicated the project does not need to be submitted for REC review.

Study design

Observational cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Evaluation of robot-assisted surgery

Interventions

1. Study design: A stepped-wedge evaluation with integrated process evaluation and economic assessment.
2. Study sites: NHS hospitals planning to introduce/expand robot-assisted surgery (RAS) services. Sites will be switched over from non-RAS to RAS-augmented services (or switch up from one level of provision to another) in random order
3. Study participants (stepped-wedge evaluation): All patients undergoing the index procedure

(RAS or otherwise) at each site across all time periods of the study

The project is embedded in normal NHS care and it is intended to be non-selective (all patients undergoing surgery for the index procedure are candidates).

4. Participants (process evaluation): Three key personnel including surgeons, theatre staff and service managers will be sampled from 6 REINFORCE sites and invited to interview. Additionally, 3-4 commissioners will also be interviewed and sampled from across the suite of trial sites. The sample size overall will be approximately 40 interviews.

Sample Size: 2,560 procedures

5. Objectives:

5.1. Impact of RAS system transformation on clinical and service delivery

5.2. Budget impact and cost-effectiveness to the NHS of the introduction of RAS at scale

5.3. Potential benefits and harms of RAS across and within speciality areas

5.4. Mechanisms of change underpinning any change in outcome, including surgeon training

Intervention Type

Other

Primary outcome measure

1. Patient level:

1.1. Disease-specific quality of life measured using procedure-specific PROM at baseline and 3 months

1.2. Overall quality of life measured using the EQ-5D questionnaire at baseline and 3 months

1.3. Overall measure of treatment effectiveness/benefit measured using a Patient Questionnaire at baseline and 3 months

1.4. Overall measure of complications inc. mortality measured using Clavien-Dindo score at 3 months

2. Surgeon/Team level:

2.1. Precision/accuracy measured using Surgeon Task Load Index (TLX) on the day of surgery

2.2. Visualisation measured using Surgeon Task Load Index (TLX) on the day of surgery

3. Organisation level:

3.1. Equipment failure measured using a Surgery Form on the day of surgery

3.2. Standardisation of operative quality measured using process evaluation interviews pre/peri/post-robot-assisted surgery (RAS) implementation

3.3. Overall economic/cost-effectiveness measured using Health Economics review throughout the study

4. Population level:

4.1 Equity of access measured using Health Economics review throughout the study

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

01/01/2022

Completion date

30/08/2025

Eligibility

Key inclusion criteria

All patients undergoing the index procedure (robot-assisted surgery or otherwise) at each site across all time periods

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 2560; UK Sample Size: 2560

Total final enrolment

2836

Key exclusion criteria

Does not meet the inclusion criteria

Date of first enrolment

01/07/2022

Date of final enrolment

31/05/2025

Locations

Countries of recruitment

England

United Kingdom

Wales

Study participating centre

University Hospital of Wales

Cardiff Urology

Dept of Urology

Cardiff & Vale University Health Board

Heath Park

Cardiff

United Kingdom

CF144XW

Study participating centre

University Hospital of Wales

Cardiff Colorectal

Dept of Gastroenterology

Cardiff & Vale University Health Board, University Hospital of Wales

Heath Park,

Cardiff

United Kingdom

CF144XW

Study participating centre

Ysbyty Gwynedd

Betsi Cadwaladr Gynaecology

Dept of Gynaecology

Penrhosgarnedd

Bangor

Gwynedd

United Kingdom

LL57 2PW

Study participating centre

University Hospital of Wales

Cardiff Gynaecology

Dept of Gynaecological Oncology

Cardiff & Vale University Health Board

Heath Park

Cardiff

United Kingdom

CF144XW

Study participating centre

Norfolk & Norwich University Hospital

Colney Lane

Colney

Norwich

United Kingdom

NR4 7UY

Study participating centre

North Bristol NHS Trust

Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
United Kingdom
BS10 5NB

Study participating centre**South Tees Hospitals NHS Foundation Trust**

James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre**Swansea Bay University Local Health Board**

Tonna Hospital
Tonna Uchaf
Tonna
Neath
United Kingdom
SA11 3LX

Study participating centre**Stockport NHS Foundation Trust**

Stepping Hill Hospital
Poplar Grove
Stockport
United Kingdom
SK2 7JE

Study participating centre**Salford Royal Hospital**

Stott Lane
Eccles
Salford
United Kingdom
M6 8HD

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Salisbury District Hospital
Salisbury District Hospital
Odstock Road
Salisbury
United Kingdom
SP2 8BJ

Study participating centre
Wrightington Hospital NHS Trust
Hall Lane
Wrightington
Wigan
United Kingdom
WN6 9EP

Study participating centre
Cwm Taf Morgannwg University Local Health Board
Dewi Sant Hospital
Albert Road
Pontypridd
United Kingdom
CF37 1LB

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
80 Newark Street
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United Kingdom
E1 2ES

Sponsor information

Organisation

University of Oxford

Sponsor details

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+44 (0)1865 270000

ctrq@admin.ox.ac.uk

Sponsor type

University/education

Website

<https://www.ox.ac.uk/>

ROR

<https://ror.org/052gg0110>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health and Care Research Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR131537

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

31/03/2026

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from the Surgical Intervention Trials Unit (SITU) at situ@ndorms.ox.ac.uk. Further details will be made available at a later date.

IPD sharing plan summary

Available on request

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|-------------------------------|-------------|--------------|------------|----------------|-----------------|
| Protocol file | version 3.0 | 20/03/2025 | 30/05/2025 | No | No |