ISRCTN18320267 https://doi.org/10.1186/ISRCTN18320267

Real-world evaluation of robot-assisted surgical services

Submission date 07/07/2022	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 10/10/2022	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 01/08/2025	**Condition category** Surgery	[_] Individual participant data [X] 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

Contact information

Type(s)
Public

Contact name
Dr Emma Blackmore-Bowes

ORCID ID
https://orcid.org/0000-0002-5848-5333

Contact details
NDORMS
University of Oxford
Nuffield Orthopaedic Centre
Oxford
United Kingdom
OX3 7HE
+44 (0)7721 491938
REINFORCE@ndorms.ox.ac.uk

Type(s)
Principal investigator

Contact name
Prof David Beard

ORCID ID

https://orcid.org/0000-0001-7884-6389

Contact details
NDORMS
University of Oxford
Nuffield Orthopaedic Centre
Oxford
United Kingdom
OX3 7HE
+44 (0)1865 227695
David.Beard@ndorms.ox.ac.uk

Type(s)
Principal investigator

Contact name
Prof Marion Campbell

ORCID ID
https://orcid.org/0000-0001-5386-4097

Contact details
Health Services Research Unit
University of Aberdeen
Foresterhill
Aberdeen
United Kingdom
AB25 2ZD
+44 (0)1224 273161
m.k.campbell@abdn.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
311223

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
There are no secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

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

Study participating centre
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
London
United Kingdom
E1 2ES

Sponsor information

Organisation
University of Oxford

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

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 3.0	20/03/2025	30/05/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes