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A research project aimed to understand and improve the shared decision-making process for patients at high risk of medical complications as they contemplate major surgery

Submission date
23/01/2024

Recruitment status
Recruiting

Registration date
30/01/2024

Overall study status
Ongoing

Last Edited
10/07/2025

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Each year in the NHS more than 250,000 high-risk patients contemplate major surgery. These patients are older and usually have chronic disease. One in three high-risk patients who choose surgery will experience medical complications leading to a long-term decline in health and quality of life. Awareness of these long-term risks is poor amongst both doctors and patients. Consequently, many high-risk patients do not receive the information they need to make an informed decision about surgery. Shared decision-making is suggested as a means of improving the way in which patients make informed decisions about their treatment. Despite a wealth of research on shared decision-making, there is little work to address the specific needs of high-risk patients contemplating major surgery, and yet this group would benefit more than any other. By combining the work conducted within the OSIRIS programme researchers have developed a decision support aid. The decision aid presents population average figures about a number of important long-term outcomes to supplement those provided as part of routine care. Patients are able to select and focus on the most important outcomes for them, while the decision aid will highlight important outcomes they may not have considered. The aim of this study is to evaluate the clinical effectiveness of a decision support intervention in a cluster randomised trial to improve shared decision-making for high-risk surgical patients and their doctors.

Who can participate?
High-risk patients aged 60 years and over who are contemplating one or more of the following surgical procedures: colorectal bowel resection for cancer, hip replacement or elective abdominal aortic aneurysm surgery

What does the study involve?
Participating hospitals are randomly allocated to one of two groups. In the intervention group hospitals doctors will use a software-based decision support intervention combined with training to promote effective shared decision-making for high-risk surgical patients. Patients and doctors will use the intervention during all decision-making encounters with the surgeons and

other healthcare staff (e.g. anaesthetists, specialist nurses). In control group hospitals, shared decision-making for high-risk patients will follow current local practices. There will be no additional training or changes to care processes for these sites.
Investigators will review a participant's medical record and contact participants by telephone to conduct brief interviews at 30 days after surgery for those participants who have undergone surgery and at 180 days after the index decision-making episode for all patients. The researchers will request hospital episode statistics and death rate data from NHS Digital (formerly HSCIC) for participants in England or an equivalent national database.

What are the possible benefits and risks of participating?
There is a small risk that patients may find it distressing to be provided with information, which may indicate poor expected outcomes in the following months and years. It is also expected that the use of the decision aid will lengthen the consultation itself (this will be measured as part of the study). There is a potential benefit of increased patient involvement in decision making resulting in reduced decision regret after surgery, and improved satisfaction with the decision-making process. Enhanced patient participation in decision-making could also potentially improve mental quality of life outcomes, which will be assessed as part of the outcome.

Where is the study run from?
Queen Mary University of London (UK)

When is the study starting and how long is it expected to run for?
October 2023 to April 2027

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Jai Vairale, admin@osiris-programme.org

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
282492

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
153646, IRAS 282492, CPMS 55538

Study information

Scientific Title
Cluster randomized trial on Optimising Shared decision-making for high-RIsk major Surgery

Acronym
OSIRIS

Study objectives
To evaluate the clinical effectiveness of a decision support intervention in a cluster randomised trial to improve shared decision making for high-risk surgical patients and their doctors.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 20/04/2023, East of England - Cambridge Central Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, United Kingdom; +44 (0)2071048384; cambridgecentral.rec@hra.nhs.uk), ref: 23/EE/0062

Study design
National multi-centre cluster randomized trial

Primary study design
Interventional

Study type(s)
Other, Quality of life

Health condition(s) or problem(s) studied
Patients who contemplate elective surgery for colorectal bowel resection for cancer, hip replacement and abdominal aortic aneurysm

Interventions
This is a complex intervention, combining training to promote effective shared decision-making for high-risk surgical patients (see above) together with a software-based decision-support intervention. This software utilises a series of computational models developed by the OSIRIS team, which incorporates modelling of patient outcomes using NHS registry data, and patient-level information on quality of life outcomes after major surgery. Patients and doctors will use the intervention during all decision-making encounters with the surgeons and other healthcare staff (e.g. anaesthetists, specialist nurses). By combining data sources from previous studies within this programme of work with NHS registry data the intervention will generate a forecast of important long-term outcomes for the patient. This forecast is presented using a clear and simple user interface with icon arrays and other patient-friendly display methods to ensure it is correctly understood. Patients will be able to select and focus on outcomes of most relevance to them, whilst the intervention could highlight important outcomes that the patient might not have considered.

This is a multi-centre, open, cluster randomized controlled trial. The study will take place in the UK across 40 NHS hospitals (approximately 20 hospitals in the intervention arm and 20 hospitals in the usual care arm). Hospitals are the units of randomisation (clusters) that will be randomized to either intervention or control with a 1:1 allocation ratio. Random permuted blocks

randomisation with block sizes of m = 4 and 2 will be used. This is a restricted randomization scheme without stratification. A manual randomization system will be used, and no adaptive element is envisaged. The code creating the randomization list will be prepared by the trial statistician. The live allocation list will be generated by an independent statistician. Manual randomization will be carried out remotely by the CTU. A member of the research team who is unblinded will be authorised to request randomization of a cluster via email to the named independent statistician who will return the allocation also via email within one working day.

In the intervention group hospitals doctors will use a software-based decision support intervention combined with training to promote effective shared decision-making for high-risk surgical patients. This software utilises a series of computational models developed by the OSIRIS team, which incorporates modelling of patient outcomes using NHS registry data, and patient-level information on quality-of-life outcomes after major surgery. Patients and doctors will use the intervention during all decision-making encounters with the surgeons and other healthcare staff (e.g. anaesthetists, specialist nurses).

In control group hospitals, shared decision-making for high-risk patients will follow current local practices. There will be no additional training or changes to care processes for these sites.

The duration of intervention will be only limited to the surgical consultation which is approximately 15-20 minutes.

Investigators will review a participant's medical record and contact participants by telephone to conduct brief interviews at 30 days after surgery for those participants who have undergone surgery and at 180 days after the index decision-making episode for all patients. To collect data on secondary outcomes and facilitate the health economic analysis, the researchers will request hospital episode statistics and mortality data from NHS Digital (formerly HSCIC) for participants in England or an equivalent national database. Prospective consent for ONS/HES (or equivalent national database) data linkage will be sought before enrolment into the trial.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
OSIRIS Decision Aid

Primary outcome(s)
1. Patients' decision regret measured using the Decision Regret Scale (DRS) at 180 days after the index decision-making episode
2. Patients' mental-health-related quality of life measured using the Mental Component Summary (MCS) score of the Short Form-12 (SF-12) at 180 days after the index decision-making episode

Key secondary outcome(s))
1. Patients' physical-health-related quality of life measured using the Physical Component Summary (PCS) score of the Short Form-12 (SF-12) at 180 days after the index decision-making episode
2. Patient satisfaction with decision-making measured using the Shared Decision-Making

Questionnaire within 48 hours of decision-making
3. Generic health-related quality of life utility, derived from participants' EQ-5D-5L questionnaire responses at 180 days after the index decision-making episode

Completion date
30/04/2027

Eligibility

Key inclusion criteria
1. Patients contemplating elective colorectal bowel resection for cancer, hip replacement or abdominal aortic aneurysm surgery
2. Age 60 years and over
3. Age-adjusted Charlson co-morbidity index ≥3

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
60 years

Upper age limit
100 years

Sex
All

Key exclusion criteria
1. Inability or refusal to provide informed consent
2. Patients expected to die within 12 months of treatment

Date of first enrolment
15/05/2025

Date of final enrolment
01/11/2026

Locations

Countries of recruitment
United Kingdom

England

Scotland

Study participating centre
NIHR CLAHRC North Thames
Barts Health NHS Trust
The Royal London Hospital
Whitechapel
London
United Kingdom
E1 1BB

Study participating centre
University Hospitals Plymouth NHS Trust
Derriford Hospital
Derriford Road
Derriford
Plymouth
United Kingdom
PL6 8DH

Study participating centre
West London NHS Trust
1 Armstrong Way
Southall
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United Kingdom
UB2 4SD

Study participating centre
North Bristol NHS Trust
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
St George's University Hospitals NHS Foundation Trust
St George's Hospital
Blackshaw Road

Tooting
London
United Kingdom
SW17 0QT

Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre
Leeds Teaching Hospitals NHS Trust
St. James's University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
Barking, Havering and Redbridge University Hospitals NHS Trust
Queens Hospital
Rom Valley Way
Romford
United Kingdom
RM7 0AG

Study participating centre
Guy's and St Thomas' NHS Foundation Trust
St Thomas' Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Queen Elizabeth Hospital

Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2GW

Study participating centre
Somerset NHS Foundation Trust
Trust Management
Lydeard House
Musgrove Park Hospital
Taunton
United Kingdom
TA1 5DA

Study participating centre
Croydon Health Services NHS Trust
Croydon University Hospital
530 London Road
Thornton Heath
United Kingdom
CR7 7YE

Study participating centre
NHS Lothian
Waverley Gate
2-4 Waterloo Place
Edinburgh
United Kingdom
EH1 3EG

Study participating centre
NHS Greater Glasgow and Clyde
J B Russell House
Gartnavel Royal Hospital
1055 Great Western Road Glasgow
Glasgow
United Kingdom
G12 0XH

Study participating centre

Mid Yorkshire Hospitals NHS Trust
Pinderfields Hospital
Aberford Road
Wakefield
United Kingdom
WF1 4DG

Study participating centre
Medway NHS Foundation Trust
Medway Maritime Hospital
Windmill Road
Gillingham
United Kingdom
ME7 5NY

Sponsor information

Organisation
Queen Mary University of London

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

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 and analysed during the current study will be available upon request. Enquiries can be sent to the data-sharing email address admin@osiris-programme.org. Ideally, the Chief Investigator (CI), Professor Rupert Pearse, should be contacted first with the enquiry at admin@osiris-programme.org for CI approval. Data would typically only be available to share at the end of the study.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2.0	28/03/2023	29/01/2024	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 2.0	20/11/2023	29/01/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes