

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	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 30/01/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 10/07/2025	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

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

Study website

<https://osiris-programme.org/>

Contact information

Type(s)

Principal Investigator

Contact name

Prof Rupert Pearse

ORCID ID

<https://orcid.org/0000-0002-4373-5934>

Contact details

ACCU Research Offices

4th Floor

Royal London Hospital

Whitechapel

London

United Kingdom

E1 1FR
+44 (0)20 3594 0351
r.pearse@qmul.ac.uk

Type(s)

Public

Contact name

Dr Priyanthi Dias

Contact details

ACCU Research Offices
4th Floor
Royal London Hospital
Whitechapel
London
United Kingdom
E1 1FR
+44 (0)20 3594 0351
p.dias@qmul.ac.uk

Type(s)

Scientific

Contact name

Mrs Jai Vairale

Contact details

ACCU Research Offices
4th Floor
Royal London Hospital
Whitechapel
London
United Kingdom
E1 1FR
+44 (0)20 3594 0351
j.vairale@qmul.ac.uk

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

282492

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Cluster randomised trial

Study setting(s)

Hospital

Study type(s)

Other, Quality of life

Participant information sheet

<https://osiris-programme.org/project-4-2>

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

Pharmaceutical study type(s)

Not Applicable

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

OSIRIS Decision Aid

Primary outcome measure

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

Secondary outcome measures

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

Overall study start date

01/10/2023

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

Age group

Adult

Lower age limit

60 Years

Upper age limit

100 Years

Sex

Both

Target number of participants

600

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**

England

Scotland

United Kingdom

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

London

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

Sponsor details

Research Services, Dept. W
c/o Mile End Post Room
327 Mile End Road
London
England

United Kingdom
E1 4NS
+44 (0)20 7882 5555
research.governance@qmul.ac.uk

Sponsor type

University/education

Website

<http://www.jrmo.org.uk/>

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

Publication and dissemination plan

Planned publication in a peer reviewed journal, conference presentations and webcasts. Intent to publish the main paper as soon as possible after completion of the trial.

Intention to publish date

30/05/2026

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
Protocol file	version 2.0	20/11/2023	29/01/2024	No	No