ISRCTN33136034 https://doi.org/10.1186/ISRCTN33136034

Wearables in perioperative care for oesophageal and gastric cancer surgery

Submission date 21/09/2026	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 22/09/2026	**Overall study status** Ongoing	
Last Edited 07/10/2026	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims

Cancer of the oesophagus (food pipe) and stomach are serious conditions that often require major surgery as part of treatment with the aim of curing the cancer. These operations are among the most complex procedures performed in cancer surgery and can carry a significant risk of complications.

Understanding a patient's physical fitness before surgery can help surgeons and anaesthetists assess their individual risk, plan their care and recovery, and provide patients with better information about what to expect.

At present, cardiopulmonary exercise testing (CPET) is commonly used to assess fitness before this type of surgery. During CPET, a patient exercises on a stationary bicycle while their heart and lung function are measured. Although CPET provides valuable information, it provides a measurement at a single point in time in a hospital environment and may not fully reflect how a person functions during their normal daily life.

Wearable devices can collect information about physical activity, heart function and sleep while people go about their usual activities at home. Measuring these continuously over several days may provide a more complete picture of a patient's physical fitness and how this changes during cancer treatment and recovery.

The main aim of this study is to investigate whether information collected using wearable devices can be used to estimate cardiorespiratory fitness as measured by CPET. In particular, we will develop and test a model that uses information from wearable devices to estimate VO_2peak, which is a measure of the body's ability to use oxygen during exercise and an important measure of physical fitness.

We will also investigate how measurements collected from wearable devices relate to patients' symptoms, physical function, quality of life and recovery throughout their treatment.

Who can participate?

Patients aged 18 years and over in registered specialist upper GI cancer surgery centres who are due for curative-intent surgery. If you are unable to undergo CPET, or have sensitivities or allergies to metals or plasters, you will not be able to participate. If you are eligible, your local care team will approach you to discuss participation in the study.

What does the study involve?
Participants will be asked to wear two wearable devices: one worn on the chest and one worn on the wrist. These devices will collect information about participants' physical activity and physiology during their normal daily lives.
Participants will wear the devices at several specified points before and after their operation so that the research team can examine how these measurements change during treatment and recovery.
Participants will also be asked to complete short questionnaires about their symptoms, physical function, quality of life and general health.
Information collected by the wearable devices will be compared with measurements obtained during participants' routine CPET assessment and other relevant clinical information.
Participation in the study will not require any additional hospital visits solely for research purposes.
Data collection for each individual participant will span about 6 months, and full follow up approximately 15 months (though this will not require participant engagement)

What are the possible benefits and risks of participating?
There are no direct benefits to taking part in this study. The results are observational and there will be no change to your treatment pathway. However, we hope results from this study could inform integration of wearable devices into cancer surgery in the future.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
October 2026 to February 2028

Who is funding the study?
Cancer Research UK

Who is the main contact?
Chief Investigator: Prof. Sheraz Markar, sheraz.markar@nds.ox.ac.uk
Lead Investigator: Ms Jessica Caterson, wearables@nds.ox.ac.uk

Plain English summary under review with external organisation

Contact information

Type(s)
Principal investigator

Contact name
Prof Sheraz Markar

Contact details
Nuffield Department of Surgical Sciences
Level 6, John Radcliffe Hospital
Oxford
United Kingdom

OX3 9DU
+44 (0)1865 612268/9
sheraz.markar@nds.ox.ac.uk

Type(s)
Public, Scientific

Contact name
Prof Sheraz Markar

Contact details
Nuffield Department of Surgical Sciences
Level 6, John Radcliffe Hospital
Oxford
United Kingdom
OX3 9DU
+44 (0)1865 612268/9
sheraz.markar@nds.ox.ac.uk

Type(s)
Scientific

Contact name
Ms Jessica Caterson

Contact details
Big Data Institute, Old Road Campus, Headington
Oxford
United Kingdom
OX3 7LF
+44 (0)1865 287770
wearables@nds.ox.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
373141

Study information

Scientific Title
Peri-Operative wearabLe-based Assessment and patient Reported Outcomes In Surgery for Oesophago-Gastric cancer (POLARIS-OG)

Acronym
POLARIS-OG

Study objectives

The primary objective of this study is to develop and internally validate a prediction model for CPET-derived peak oxygen uptake, measured as VO_2peak, using wearable-derived physiological and activity parameters collected during real-world monitoring.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/10/2026, East Midlands – Derby Research Ethics Committee (Health Research Authority (HRA), 2 Redman Place, London, EC20 1JQ, United Kingdom; +44 (0)207 104 8000; derby.rec@hra.nhs.uk), ref: 26/EM/0219

Primary study design
Observational

Secondary study design
Cohort study

Study type(s)

Health condition(s) or problem(s) studied
Oesophageal or gastric cancer

Interventions
POLARIS-OG is a prospective, multi-centre observational study evaluating the relationship between wearable-derived physiological and activity measures, CPET-derived cardiorespiratory fitness, patient-reported outcomes and postoperative recovery in patients undergoing treatment for oesophago-gastric cancer. The primary analysis will develop and internally validate a model that predicts CPET-derived VO2peak using wearable-derived physiological and activity parameters collected during real-world monitoring. In addition to the primary prediction modelling objective, the study will evaluate the peri-operative trajectory of wearable-derived physiological function and activity across the treatment pathway. Wearable-derived measures will be compared with CPET variables and patient-reported outcome measures, and exploratory associations between wearable-derived parameters and clinical outcomes will be investigated.

Participants will be recruited from Upper Gastrointestinal Cancer Centres across England. Recruiting sites will include tertiary referral hospitals and specialist cancer surgery centres responsible for the diagnosis, neoadjuvant treatment, and surgical management of oesophagogastric cancer. Future recruitment may expand to additional centres in Wales, Scotland, and selected European centres in Germany and the Netherlands.

Potential participants will be identified during routine outpatient or multidisciplinary team (MDT) pathways when a clinical decision has been made to proceed with curative-intent surgery. Recruitment, consent, and clinical follow-up will be undertaken locally by participating site teams. Wearable devices will be distributed centrally by the University of Oxford via mail delivery.

Participants will be involved in the active study period for approximately 6 months, with additional clinical follow-up through review of routine medical records continuing until 1 year after surgery (approximately 15 months total study duration). Eligible patients will be

approached in outpatient clinics following diagnosis and treatment planning and will have up to 3 weeks to consider participation, or until 7 days prior to commencing neoadjuvant chemotherapy, whichever occurs sooner.

Following consent, participants will complete wearable monitoring and questionnaires at four study timepoints:
1. Baseline (at recruitment): chest-worn and wrist-worn devices worn continuously for 7 days; completion of MCTQ plus EQ-5D-5L, SF-36, and wearable experience questionnaire
2. Post-neoadjuvant therapy / pre-surgery: repeat 7-day monitoring using chest-worn and wrist-worn devices; CPET performed as part of standard care; repeat questionnaires
3. 30 days following surgery: wrist-worn device only for 7 days; repeat questionnaires
4. 90 days following surgery: wrist-worn device only for 7 days; repeat questionnaires

Wearable devices will be posted directly to participants together with written and diagrammatic instructions and pre-paid packaging for device return. No additional hospital visits will be required specifically for study participation.

Physiological and activity data will be collected using two wearable devices:
1. Bittium Faros 180 chest-worn device — collecting single-lead electrocardiogram (ECG) and triaxial accelerometry data
2. Garmin® wrist-worn device – collecting photoplethysmography (PPG) derived heart rate and raw triaxial accelerometry data

The MCTQ will be used at baseline to establish the participant's routine sleep habits. Patient-reported outcomes will be collected using the validated questionnaires EQ-5D-5L and SF-36. A wearable acceptability and user experience questionnaire will also be administered to assess participant usability and tolerability of the devices.

Clinical data, including CPET variables (e.g., anaerobic threshold and VO2peak), cancer characteristics, treatment details, surgical outcomes, and postoperative recovery data, will be obtained from routine clinical records and uploaded by local research teams into REDCap electronic case report forms (eCRFs).

These methods have been selected to enable longitudinal assessment of physiological function, physical activity, recovery trajectories, and patient experience within participants' usual living environments, while minimising participant burden and avoiding unnecessary hospital visits. The wearable devices are designed for simple self-application and will not require Bluetooth pairing, smartphone connectivity, or participant-led data transfer. In addition, questionnaires will be available in both electronic and paper formats to ensure broad accessibility and reduce the risk of excluding participants based on digital access or technological literacy.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Bittium Faros 180 chest-worn device, Garmin® wrist-worn device

Primary outcome(s)

1. Wearable-derived VO_2peak measured using an internally validated algorithm (features will include a combination of steps, accelerometry, heart rate, heart rate variability, and sleep) at pre-operative (at the same time as CPET)

Key secondary outcome(s)
1. Wearable-derived anaerobic threshold derived from an an internally validate algorithm (features will include a combination of steps, accelerometry, heart rate, heart rate variability, and sleep) measured using wearable at pre-operative (at the same time as CPET)

2. Trajectory of wearable-derived physiological and activity parameters including activity time, daily step count, chronotropic incompetence, heart rate variability, resting heart rate, heart rate reserve, and sleep metrics measured using chest- and wrist-worn wearable devices during real-world monitoring at baseline, post-neoadjuvant chemotherapy, 30-days and 90-days postoperatively

3. Wearable-derived VO2peak measured using other 'off the shelf' publicly available algorithms at pre-operative (at the same time as CPET)

4. Health-related quality of life and health utility measured using EQ-5D-5L and SF-36 at baseline, post-neoadjuvant chemotherapy, 30- and 90-day post-operation

5. The usability and acceptability of wearable devices measured using device wear-time adherence and participant-reported acceptability and tolerability at baseline, post-neoadjuvant chemotherapy, 30- and 90-day postoperation

Completion date
29/02/2028

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study
2. Male or Female, aged 18 years or above
3. Participants due to undergo elective oesophagogastric cancer resection surgery (oesophageal, oesophagogastric junction or gastric cancer)

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Urgent or emergency surgery
2. Poor baseline mobility (e.g. wheelchair bound)
3. Inability to undergo assessment with wearables or cardiopulmonary exercise test (CPET) as defined by national guidelines (e.g. active myocardial ischaemia, decompensated heart failure, uncontrolled/untreated arrhythmias, aortic dissection or suspected aortic dissection, endo/peri/myocarditis, acute exacerbation of COPD or asthma, acute pulmonary oedema, acute respiratory failure and pulmonary embolism)
4. Metal allergy or sensitivity to medical adhesives

Date of first enrolment
01/10/2026

Date of final enrolment
31/12/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Nuffield Department of Surgical Sciences, University of Oxford
Level 6, John Radcliffe Hospital
Oxford
England
OX3 9DU

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.1	21/09/2026	07/10/2026	No	No