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Are patient outcomes improved by surgery that uses a glowing dye to illuminate a cancerous tumour?

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02/10/2023

Recruitment status
Suspended

Registration date
20/10/2023

Overall study status
Ongoing

Last Edited
01/05/2026

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Sarcomas are rare types of cancer, making up only 1% of all cancer cases in the UK, with about 5300 new diagnoses each year. What sets sarcomas apart is that they affect people across a wide range of ages, especially younger individuals. On average, patients are diagnosed with sarcomas at the age of 56. Unfortunately, the survival rates for sarcomas aren't great, with only about 65% of patients surviving five years after diagnosis. For those with higher grade sarcomas, the survival rate drops to 50%, and these numbers haven't improved much over the last 30 years.

The main treatment for sarcomas is surgery, with the goal of removing the tumor completely while preserving as much healthy tissue as possible. But here's the problem: during surgery, it's often challenging for the surgeon to distinguish between the tumor and healthy tissue by sight and touch alone.

One of the most critical factors in predicting a patient's outcome after surgery is the "resection margin." This margin is determined by pathologists who examine the removed tissue in a lab. A "negative margin" means that the tumor was completely surrounded by healthy tissue, suggesting that no cancer was left behind. On the other hand, a "positive margin" means that tumor cells are still present at the edge of the removed tissue. This is a bad sign because it's linked to a higher risk of cancer recurrence and poorer overall survival for the patient.

To improve outcomes for sarcoma patients, we're exploring a promising technology called fluorescence-guided surgery (FGS). FGS involves injecting a special dye called indocyanine green (ICG) into the patient before surgery. The tumor absorbs this dye, making it glow when viewed through a special camera during surgery. ICG has been used safely for years in other medical procedures. Recent research has shown that it can also help surgeons identify healthy tissue from diseased or poorly vascularized tissue during surgery.

A recent case series suggested that using FGS with ICG for high-grade sarcoma removal may reduce the rate of positive margins. Therefore, we're conducting a randomized controlled trial to investigate this further. This trial will include sarcoma patients of all ages and subtypes,

except low-grade sarcomas that don't fluoresce. It's an important step toward improving outcomes for sarcoma patients by reducing the risk of positive margins, which are associated with worse short-term and long-term outcomes.

Our study aims to compare the rate of positive margins between FGS using ICG and standard surgery. This is crucial because positive margins are linked to a higher risk of cancer recurrence and poorer survival for patients. Ultimately, this research could lead to better surgical techniques and better outcomes for sarcoma patients.

Who can participate?
Any individual of any age who has been diagnosed with an intermediate to high-grade sarcoma in their bones or soft tissues, and can undergo surgery with the aim of curing the disease, can join the study. However, if someone is currently pregnant or breastfeeding, they won't be able to participate. Also, those with certain conditions won't be eligible. This includes individuals with tumors that have come back, tumors located in specific places like the inner organs, abdomen, or brain, anyone who's allergic to a substance called ICG, iodine, iodine dyes, or shellfish, and those who can't provide written consent for the study.

What does the study involve?
Once a patient has agreed to participate in the trial, the research team will use a method called "randomization" to decide which group they will be in. Both the patient and their doctor will be informed about this randomization outcome.

If a participant is placed in the group that gets the special surgery called "Fluorescence Guided Surgery using Indocyanine Green" (FGS with ICG), they will need to come to the hospital one day before their surgery.

On the other hand, participants in the control group will come to the hospital as inpatients either on the day before their surgery or on the day of surgery, depending on what their care team decides based on their specific medical needs.

For those in the FGS with ICG group, they'll come to the hospital a day before surgery to receive an injection of ICG dye. A nurse or doctor will give this injection through a vein, and it will be done 12-24 hours before the actual surgery.

For participants in the control group, they will receive the standard surgery. This involves surgeons using pre-operative images to locate the sarcoma in the body and using their hands to feel for the edges of the tumor to help with the removal.

However, participants in the FGS with ICG group will have an extra step during surgery. They will also use a special near-infrared camera that shows real-time images of the tumor, which has absorbed the ICG dye and glows. The surgeon will use these images to guide them during the tumor removal.

After the surgery, all participants will receive the usual post-operative care, just like any other patient in a standard care setting.

We will gather information about the surgery from the surgeon, including how long it took, how much of the tumor they think might still be in the patient, if there were any complications during surgery, and if using the camera had any impact on the surgeon's decisions.

Additionally, at baseline and 1, 3, 6, and 12 months after the surgery, participants will be asked to fill out some questionnaires like EQ-5D-5L/EQ-5D-Y and TESS/pTESS (if applicable) to help us track their progress and well-being.

What are the possible benefits and risks of participating?
There is no direct benefit to the participants for taking part in the trial. However, they may have access to a treatment (i.e., FGS using ICG) not normally provided as standard of care on the NHS. Patients in the future may potentially benefit from the information gained.

Both surgical methods for resection of sarcoma are used in NHS hospitals although FGS using ICG is not currently standard of care. Therefore the risk to patients taking part in the trial are no greater than their risks of having the surgery outside of the trial.
The burden to the participants are considered to be low. Aside from the surgery and follow up appointments at 6- and 12-months, which would be taking place in side or outside the trial, participants will be asked to complete some questionnaires. All participants will be asked to complete the quality of life questionnaire the EQ-5D-5L/ EQ-5D-Y and if they have had a sarcoma effect on of their extremities they will also be asked to complete the Toronto Extremity Salvage Score. Both questionnaires take about 10-15 minutes each to complete. The questionnaires will be completed at baseline, then at 1-, 3-, 6- and 12 months post surgery. Completing the questionnaires will not require extra hospital visits and will be sent to participants electronically.

Where is the study run from?
Newcastle Clinical Trials Unit, part of Newcastle University (UK)

When is the study starting and how long is it expected to run for?
July 2023 to April 2028

Who is funding the study?
1. NIHR Efficacy and Mechanism Evaluation Programme (UK)
2. Stryker (UK)

Who is the main contact?
sarcosight@newcastle.ac.uk

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-of-fluorescence-guided-surgery-for-sarcoma-sarcosight

Contact information

Type(s)
Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
1012390

Central Portfolio Management System (CPMS)
58058

National Institute for Health and Care Research (NIHR)
134276

Study information

Scientific Title
SarcoSIGHT: a randomised controlled trial of fluorescence guided sarcoma surgery versus the standard of care

Acronym
SarcoSIGHT

Study objectives
Fluorescence guided surgery (FGS) using indocyanine green (ICG) will reduce the unexpected positive margin (UPM) rate compared to the current standard of care (SoC) in patients with a histologically confirmed diagnosis of intermediate to high-grade bone or soft tissue sarcoma suitable for curative resection.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 21/09/2023, East Midlands - Nottingham 1 Research Ethics Committee (Health Research Authority, 2 Redman Place, London, E20 1JQ, United Kingdom; +44 (0)207 104 8000; Nottingham1.rec@hra.nhs.uk), ref: 23/EM/0212

2. approved 08/12/2025, Yorkshire & The Humber - Sheffield Research Ethics Committee (Health Research Authority, 2 Redman Place, London, E20 1JQ, United Kingdom; +44 (0)207 104 8000;; sheffield.rec@hra.nhs.uk), ref: 25/YH/0224

Study design
Prospective two-arm open-label UK multi-centre randomized controlled trial

Primary study design
Interventional

Study type(s)
Efficacy, Treatment

Health condition(s) or problem(s) studied
Patients with intermediate to high-grade bone or soft tissue sarcoma.

Interventions
Patients of all ages with a histologically confirmed diagnosis of intermediate to high grade sarcoma will be screened for eligibility. Eligible patients will be randomised in a 1:1 ratio to standard of care surgery versus fluorescence guided surgery (FGS) using Indocyanine Green (ICG), stratified by acceptable/close positive margin, sarcoma sub-type and treating centre. Randomisation will be done using Sealed Envelope, which is a central secure 24-hour web-based randomisation system with concealed allocation.

This is an unblinded trial, however the histopathology staff and senior statistician will be blind to the surgery type received by the patient. This is to allow for blinded measurement and analysis of primary outcome.

Patients randomised to standard of care will undergo surgical resection without pre-operative ICG administration or intra-operative fluorescence guidance. This will be performed as per the preferences of the operating surgeon but will be planned based on pre-operative imaging of the tumour, with appropriate skin mark-up.

Patients randomised to the FGS arm will be administered 1mg/kg ICG intravenously 12-24 hours prior to the procedure. The skin will be marked based on pre-operative imaging as per standard of care and prepped using chlorhexidine to reduce background fluorescence from iodine-based solutions. The surgeon should then proceed with their planned resection as per standard of care. As they proceed with the resection they must use the Stryker SPY-PHI camera to image areas of interest; interpretation of images and any influence on operative decision making is at the discretion of the operating surgeon. If fluorescence changes the procedure at any time, further images (in white light, overlay mode, SPY fluorescence mode and colour segmented overlay mode) should be taken as appropriate, and this must be noted by the operating room team. Following the resection, both the resected specimen and the wound bed should be imaged (in all modes as above), and a decision made regarding the requirement for the removal of any further tissue.

Resected specimens should then be sent to the pathology laboratory to undergo trimming and margin assessment by a histopathologist as per standard practice. Once the pathology report is available and discussed at the MDT, the surgical team will complete a pathology specific trial report form, documenting the margin status. In the case of a UPM, plans for re-excision should also be documented, and the results of this also added to the 6- month follow up CRF. It is important to note that a single case may have both acceptable and unexpected positive margins if a positive margin is present in an area not adjacent to the preserved structure; in this case it should be recorded as a UPM.

Intervention Type
Mixed

Primary outcome(s)
The unexpected positive margin (UPM) rate, defined as the percentage of patients with an unexpected positive margin. The margin status of each tumour will be taken from the pathology report for each patient enrolled in the trial. This will be recorded at six months post-surgery and will be classified according to the R classification system. Positive margins will be classified as the visualisation of tumour cells at the inked margin and will then be classified as acceptable or unexpected. The UPM rate for each arm will be defined by calculating the percentage of patients in that arm with a UPM on histopathological assessment of the resection specimen. If a negative margin is recorded, the size of the closest margin should be recorded in millimetres

Key secondary outcome(s))
Current key exclusion criteria as of 21/04/2026:

Measured using patient records unless noted otherwise:
1. The difference in rate of AEs/SAEs reported between two groups
2. The difference in rate of ADEs/ SADEs reported between two groups
3. The difference in rates of surgery related AEs/SAEs reported between the two groups.
4. Between group differences in length of index operation measured in minutes
5. Difference in length of impatient stay in days
6. The percentage of operations in which the surgeon stated FGS changed their planned resection
7. The difference in rate of local recurrence at 12 months
8. The difference in rate of regional/distal recurrence at 12 months
9. The difference in rate of survival between the two groups
10. Adjuvant and neo-adjuvant therapy rates will include radiation therapy and/or chemotherapy. The type and frequency of therapy will be recorded
11. The difference in global and individual scores on EQ-5D-5L/EQ-5D-Y
12. The difference in scores on the Toronto extremity salvage score (TESS)/ Paediatric Toronto extremity salvage score (pTESS)
Exploratory Outcomes
1. Fluorescence microscopy to assess extracellular and cellular ICG spatial orientation in tumour tissue versus surrounding normal
tissues
2. Fluorescence mapping will be performed on all images taken during the trial and correlated with the pathological margin
assessments

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Previous key exclusion criteria:

Measured using patient records unless noted otherwise:
1. Rates of intra- and postoperative complications as recorded in the clinical notes.
2. Length of operation in minutes
3. Length of inpatient stay in days.
4. The percentage of operations in which the surgeon stated FGS changed their planned resection.
5. Rate of local recurrence at 12 months.
6. Rate of regional/distal recurrence at 12 months.
7. Rate of overall survival at 12 months.
8. Rates of adjuvant and neo-adjuvant therapies as per clinical notes.
9. Quality of life measured using EQ-5D-5L/EQ-5D-Y at baseline and months 1-, 3-, 6- and 12 months post surgery
10. Disability measured using the Toronto extremity salvage score (TESS)/ Paediatric Toronto extremity salvage score (pTESS) at baseline and months 1-, 3-, 6- and 12 months post surgery

Completion date
30/04/2028

Eligibility

Key inclusion criteria
Current key inclusion criteria as of 21/04/2026:

1. Patients of any age
2. Capacity to provide written, informed consent (or parent/carer if <16 years of age; legal representative if an adult lacking capacity)
3. Histologically confirmed diagnosis of intermediate to high grade sarcoma
4. Amenable to surgical resection as a part of curative intent for the patient

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Previous key inclusion criteria:

1. Patients of any age
2. Capacity to provide written, informed consent (or legal guardian if <16 years of age)
3. Histologically confirmed diagnosis of intermediate to high grade sarcoma
4. Amenable to curative surgical resection

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
All

Lower age limit
0 years

Upper age limit
120 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Current key exclusion criteria as of 21/04/2026:

1. Due for surgery with palliative intent
2. Recurrent tumours
3. Intracranial, retroperitoneal, and visceral anatomical locations
4. A woman of childbearing potential* who is currently pregnant (as confirmed by urine pregnancy test)
5. A woman who is currently breastfeeding
6. Known allergy to iodine, iodine dyes or shellfish.
7. Patients with hyper-thyroidism or autonomic thyroid adenomas
8. Premature infants/neonates with exchange transfusion indication due to hyperbilirubinemia
9. Previously known allergy or poor toleration of ICG

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Previous key exclusion criteria:

1. Tumour not amenable to curative resection or recommended for non-operative management
2. Recurrent tumours
3. Intracranial, retroperitoneal and visceral anatomical locations
4. Females that are currently pregnant (as confirmed by urine pregnancy test)
5. Females who are currently breastfeeding
6. Known allergy to ICG, iodine, iodine dyes or shellfish.
7. Unable to provide written, informed consent

Date of first enrolment
01/03/2024

Date of final enrolment
30/04/2027

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

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

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
Manchester
England
M13 9WL

Study participating centre
The Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Foundation Trust
Gobowen
Oswestry
England
SY10 7AG

Study participating centre
The Royal Orthopaedic Hospital NHS Foundation Trust
The Woodlands
Bristol Road South
Northfield
Birmingham
England
B31 2AP

Study participating centre
Birmingham Women's and Children's NHS Foundation Trust
Steelhouse Lane
Birmingham

England
B4 6NH

Study participating centre
Royal National Orthopaedic Hospital NHS Trust
Brockley Hill
Stanmore
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HA7 4LP

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

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

Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
Northern General Hospital
Herries Road
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S5 7AU

Study participating centre
Nottingham University Hospitals NHS Trust
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NG7 2UH

Study participating centre
North Bristol NHS Trust
Southmead Hospital
Southmead Road
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BS10 5NB

Study participating centre
University Hospitals Plymouth NHS Trust
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PL6 8DH

Study participating centre
Royal Devon University Healthcare NHS Foundation Trust
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EX2 5DW

Study participating centre
The Royal Marsden Hospital
Fulham Road
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SW3 6JJ

Study participating centre
The Christie NHS Foundation Trust
550 Wilmslow Road
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M20 4BX

Study participating centre
Swansea Bay University Local Health Board
One Talbot Gateway, Seaway Drive
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SA12 7BR

Study participating centre
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AB15 6RE

Study participating centre
NHS Lothian
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2-4 Waterloo Place
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EH1 3EG

Study participating centre
NHS Greater Glasgow and Clyde
J B Russell House
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1055 Great Western Road Glasgow
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G12 0XH

Study participating centre
Belfast Health and Social Care Trust
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Lisburn Road
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BT9 7AB

Study participating centre
South Eastern Health and Social Care Trust
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Upper Newtownards Road
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Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

ROR
https://ror.org/05p40t847

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

Funder Name
Stryker

Alternative Name(s)
Stryker Corporation, Orthopedic Frame Company

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The data set will be the property of the CI. Any requests to access the final trial dataset may be considered under the NCTU data sharing policy.

The final data set will be stored electronically in secure files on the Newcastle University server. Initially the final trial data set will be accessible only to the trial statisticians. Upon completion of the final analysis the final trial data set will be made available to the CI.

Following completion of the analysis, relevant copies of the data will be sent to the PI at each site. It will remain the responsibility of the PI to ensure that the site-specific data set is securely stored and retained for the specified arching period.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes