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The effect of intermittent inflation of an arm tourniquet (remote ischaemic preconditioning) on patient outcomes after surgery for intra-abdominal cancer (RIPCa) - a pilot study

Submission date
05/08/2019

Recruitment status
No longer recruiting

Registration date
26/10/2021

Overall study status
Completed

Last Edited
07/06/2023

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
During surgery the body goes through physiological changes that put it under stress and require the presence of adequate blood flow in order to avoid the development of complications. Previous studies have shown that if the blood flow to an arm is briefly reduced (like when a blood pressure cuff is inflated), then the stress to the body is less and the complications are reduced. This technique is called remote ischaemic preconditioning or RIPC. These studies have been done mainly in cardiac surgery. There are only a few studies using RIPC in cancer surgery.

Who can participate?
Patients who are scheduled to undergo surgery for intra-abdominal (colorectal, pancreatic, gynaecological) cancer and who are at increased risk of developing complications after their operation will be invited to take part in the study.

What does the study involve?
Patients will be randomly allocated to either RIPC or standard group. After induction of anaesthesia, the patients in the RIPC group will have a blood pressure cuff around one of their arms inflated 3 times for 5 minutes at a time followed by a 5-minute deflation. The patients in the standard group will not undergo this cuff inflation and deflation. We will also collect blood and urine samples that will be used for measurement of markers of kidney function (urinary biomarkers) and blood flow to the heart (troponin). All patients will be monitored for the development of complications such as infection, bleeding, heart or kidney dysfunction during hospital stay and then via telephone at 1, 3 and 6 months after the operation. The kidney function will also be assessed via a blood test at the routine surgical follow up.

What are the possible benefits and risks of participating?
The intervention used in the study may reduce complications after the operation. This may have beneficial effects that extend beyond the immediate period following surgery. The information we get from this study may also help us in the future identify patients at risk of complications

early and therefore allow us to take action to prevent these complications occurring.
We do not anticipate any significant side effects of having the cuff applied. The orthopaedic surgeons commonly use a similar cuff for much longer periods. In these cases, side effects are rare and may include pain in the arm, tingling and numbness and rarely damage to the nerves or blood vessels of the arm. However, we are applying the cuff for a continuous period of 5 minutes only.

Where is the study run from?
Royal Surrey County Hospital, UK

When is the study starting and how long is it expected to run for?
April 2019 to November 2020

Who is funding the study?
Inspire Cancer Research Foundation

Who is the main contact?
1. Dr Kat Papadopulou,
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
243707

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 243707, CPMS 38780

Study information

Scientific Title
Remote Ischaemic Preconditioning in intra-abdominal Cancer surgery (RIPCa) – a pilot study

Acronym
RIPCa

Study objectives
Remote ischaemic preconditioning (RIPC) is associated with better outcomes following surgery for intra-abdominal cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/04/2019, London -Fulham Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ; +44207 104 8235; nrescommittee.london-fulham@nhs.net) ref:18/LO/1513

Study design
Single-centre interventional double-blinded pilot randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)

Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Elective surgery for intra-abdominal cancer

Interventions
Participants allocated to the intervention group will receive remote ischaemic preconditioning (RIPC) in the anaesthetic room after induction of general anaesthesia and prior to skin incision. RIPC will be provided by inflation of an appropriate size tourniquet placed at an upper limb. The tourniquet will be inflated at a pressure of 200 mmHg for five minutes, then deflated for five minutes and the process will be repeated for a total of three times.

Participants randomized to the control group will have a tourniquet placed at an upper limb but not inflated.

In both groups, the surgical procedure and post-surgical care will proceed as per the standard of care.

The randomisation process will be done using an online randomisation tool and the method of sequentially numbered opaque sealed envelopes will be used. Each envelope will be opened in the anaesthetic room after induction of general anaesthesia.

Intervention Type
Procedure/Surgery

Primary outcome measure
Feasibility of substantive trial measured using the recruitment rate of 50 participants over 12 months. Feasibility assessment will include the proportion of potentially eligible patients that are recruited to the study and followed up at the specified timepoints (days 2, 3, 5 30, 90, 180) and the proportion of required blood and urine samples that are collected and analysed.

Secondary outcome measures
1. Postoperative morbidity (as defined by Postoperative Morbidity Survey or POMS on days 2, 3, and 5 and the American College of Surgeons National Safety Quality Improvement Program or ACS NSQIP within 30 days, 90 days and 6 months postoperatively).
2. High sensitivity Troponin pre-operatively and on the first postoperative day
3. Renal stress biomarkers (urinary TIMP-2 * IGFBP-7) measured at 4 hours postoperatively
4. Hospital length of stay
5. Quality of life measured using the EQ-5D-5L questionnaire
6. Acceptability of the study assessed at the out of hospital follow-up

Overall study start date
08/01/2018

Completion date
30/11/2020

Eligibility

Key inclusion criteria
Adults 18 years or over undergoing elective surgery for intra-abdominal cancer (colorectal, pancreatic or gynaecological) under general anaesthesia, and at increased risk of postoperative complications, as defined by the American College of Surgeons National Surgical Quality Improvement Project (ACS NSQIP) calculated risk of morbidity >10%

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

Total final enrolment
47

Key exclusion criteria
1. Patients unable to give consent
2. Day surgery
3. Emergency surgery
4. Total intravenous anaesthesia
5. Pregnancy
6. Recent (< 1 month) or ongoing acute myocardial infarction
7. Unstable or ongoing angina
8. Peripheral vascular disease
9. History of vascular intervention in the limb to be used for RIPC
10. Thromboembolic disease
11. Significant coagulopathy or bleeding diathesis
12. Sickle cell disease
13. Neuromuscular diseases
14. Use of sulfonylureas or nicorandil

Date of first enrolment
26/04/2019

Date of final enrolment
26/04/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Surrey County Hospital
Egerton Road
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Sponsor information

Organisation
Royal Surrey County Hospital

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Sponsor type
Hospital/treatment centre

Website
https://www.royalsurrey.nhs.uk

ROR
https://ror.org/02w7x5c08

Funder(s)

Funder type
Charity

Funder Name
Inspire Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The results of this study will be submitted for publication at peer-reviewed journals and presented at relevant conferences

Intention to publish date
10/12/2021

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		23/03/2022	18/07/2022	Yes	No