ISRCTN96363642 https://doi.org/10.1186/ISRCTN96363642

Do patients having major abdominal surgery exhibit significant muscle wasting?

Submission date
01/04/2015

Recruitment status
No longer recruiting

Registration date
06/05/2015

Overall study status
Completed

Last Edited
11/10/2019

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Patients who have major abdominal surgery may require some of their care to be delivered on the intensive care unit (ICU), particularly if they have complications of surgery or have significant pre-existing health problems. Patients on ICU are known to be at risk of developing muscle wasting. This means due to a stress response the proteins in the muscle start to break down. This can cause a decrease in muscle mass and/or weakness. This may hinder their rehabilitation, and their ability to breathe without the aid of a ventilator. It is known that some patients who have cardiac surgery also develop muscle wasting but it is unclear if other types of surgery can have the same effects. The aim of this study is to observe people around the time of (before and after) major abdominal surgery and collect information about changes in mass of a leg muscle.

Who can participate?
People over 18 having major abdominal surgery as a treatment for cancer.

What does the study involve?
You receive exactly the same treatment as if you are not participating but routine clinical data is collected, such as information about your surgery and recovery. Additionally the strength of your grip is measured, as is how effective you are at sniffing. We use an ultrasound machine to measure the size of a muscle in your leg. There are additional blood tests. At the end of surgery we place a small device that looks like a wristwatch, on your ankle. The device measures your activity and stays there until you are ready to leave hospital. With the help of your nurse we collect your urine for the first 24 hours following your surgery. During your recovery we visit you on alternate days to see how you are. On day 7 after your surgery or before you leave hospital we ask you to do a 6 minute walking distance test and some other simple exercises to assess your exercise capacity. If you are willing, we want to repeat the tests 6 weeks after your surgery (not the blood test).

What are the possible benefits and risks of participating?
Participation in the study will not necessarily benefit you during your hospital stay. The information we get from this study will improve our understanding of muscle wasting and weakness and its effect on recovery from major surgery. This may lead to the development of treatments to improve recovery from major surgery. You will have additional blood test and this

will be performed by an experienced practitioner. It is associated with slight pain and some very low risks: sometimes a bruise may develop. Occasionally it can be difficult to find a vein and it may unfortunately take more than one attempt to obtain a sample. As with any wound, an infection may develop where the needle was put in, this is very unlikely. Some people feel faint during a blood test. You will be encouraged to lie down if this happens to prevent fainting. Nerve injuries are very rare.

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?
January 2014 to September 2017

Who is funding the study?
Royal Surrey County Hospital Foundation Trust (UK)

Who is the main contact?
Dr Ben Creagh-Brown (UK)
bencb@nhs.net

Contact information

Type(s)
Scientific

Contact name
Dr Ben Creagh-Brown

ORCID ID
http://orcid.org/0000-0002-4397-1232

Contact details
Royal Surrey County Hospital
Egerton Road
Guildford
United Kingdom
GU2 7XX

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
v4.1

Study information

Scientific Title
Muscle wAsting in Major Abdominal Surgery (MAMAS)

Acronym
MAMAS

Study objectives
Muscle wasting is a recognised complication of critical illness and it means the development of loss of muscle mass and of muscle strength. When mild this may be clinically silent or, when more profound, can manifest as failure to breathe effectively without support from a ventilator and/or a failure to be able to mobilise or even sit without assistance. Patients undergoing major elective surgery may develop acute muscle wasting (myopenia) and associated weakness that impedes their recovery. By characterising the myopenia, its risk factors and its consequences, we will improve our understanding which will inform future studies aimed at developing studies to establish effective prevention and treatment. Furthermore, peri-operative muscle wasting provides an unrivalled model that can provide mechanistic insight into Intensive care unit-acquired weakness (ICU-AW).

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London, 01/04/2015, ref: 15/LO/0139

Study design
Prospective single-centre observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Muscle wasting disease (myopenia)

Interventions
1. The cross sectional area of the rectus femoris muscle (RFCSA) will be measured using an ultrasound machine before surgery and on day 7 (or day of discharge if earlier)
2. Handgrip strength (HGS) and sniff nasal inspiratory pressure (SNIP) will be measured before surgery and on day 7 (or day of discharge if earlier)
3. We will place an actigraph device on participants' ankle at the end of their procedure and

collect data of activity for 7 days following surgery
4. Blood samples will be taken after induction of anaesthesia but before surgery starts, at the end of surgery and on day 7 or discharge
5. We will collect urine for 24 hours post-operatively
6. Clinical outcome measures will be checked and recorded on day 1, 3, 5 and 7 post-operatively
7. On day 7 (or discharge) participants will have a functional assessment of their muscle power and exercise capacity.
8. The patients will be followed-up at 6 weeks for assessment of RFCSA, HGS, SNIP and muscle power and exercise capacity

Intervention Type
Mixed

Primary outcome measure
1. Characterise changes in muscle size and strength in patients undergoing major elective abdominal surgery for cancer at 2 stages: pre-operative and at day 7

Secondary outcome measures
1. Establish the relationship between observed changes in muscle size and strength
2. Establish the clinical sequelae of muscle wasting and weakness in relation to clinical outcomes
3. Elucidate risk factors for muscle wasting and muscle weakness
4. Assess relationship between muscle wasting and weakness
5. Assess recovery of muscle wasting and weakness between hospital discharge and week 6 and to elucidate risk factors for persistent or progressive change

Overall study start date
01/01/2014

Completion date
31/01/2019

Eligibility

Key inclusion criteria
Current inclusion criteria as of 26/11/2018:
1. Patients presenting to Royal Surrey County Hospital (RSCH) for elective major abdominal surgery for cancer with predicted duration of surgery of >3 hours, such as resection of pancreas and small bowel or resection of organs of the female reproductive tract
2. Provide informed consent
3. Age ≥18 years

Previous inclusion criteria:
1. Patients presenting to Royal Surrey County Hospital (RSCH) for elective major abdominal surgery for cancer (e.g. resection of whole/part of colon, rectum, stomach, oesophagus, liver, pancreas and small bowel; or resection of organs of the female reproductive tract) with predicted duration of surgery of >3 hours
2. Provide informed consent
3. Age ≥18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
52

Key exclusion criteria
Current exclusion criteria as of 26/11/2018:
1. Neuromuscular condition
2. Invasively ventilated pre-operatively
3. Recent (<1 month) surgery, other than for the purposes of diagnosis/staging.
4. Unlikely to survive 1 month post-operatively

Previous exclusion criteria:
1. Neuromuscular condition
2. Invasively ventilated pre-op
3. Recent (<1 month) surgery, other than for the purposes of diagnosis/staging.
4. Unlikely to survive 1 month post-operatively
5. Obesity

Date of first enrolment
21/03/2016

Date of final enrolment
30/11/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Surrey County Hospital NHS Foundation Trust
Egerton Road
Guildford
United Kingdom
GU2 7XX

Sponsor information

Organisation
Royal Surrey County Hospital Foundation Trust

Sponsor details
Egerton Road
Guildford
England
United Kingdom
GU2 7XX
+44 (0) 1483 571122
rsc-tr.communications@nhs.net

Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/050bd8661

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Surrey Peri-operative Anaesthesia Critical care collaborative Research (SPACeR) group (www.spacer.org.uk) based at Royal Surrey County Hospital (UK)

Results and Publications

Publication and dissemination plan
Publication in peer-reviewed journals and presented at international surgical, anaesthetic and perioperative medicine conferences. It will also be a part of a PhD thesis.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Dr Ben Creagh-Brown (bencb@nhs.net). During the study all study documents and electronic de-identified participant data will be stored securely at Royal Surrey County Hospital. Following completion of the study all documents (paper and electronic) will be archived and retained securely for 5 years.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No