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Microvascular monitoring during liver resection surgery - a pilot study

Submission date
07/11/2014

Recruitment status
No longer recruiting

Registration date
20/03/2015

Overall study status
Completed

Last Edited
17/01/2017

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
During liver resection surgery the medical team will manipulate the circulation (blood pressure etc) in order to minimise blood loss. Routine clinical monitoring during liver resection surgery includes heart rate, blood pressure and measures of cardiac output. Microcirculatory monitoring is an investigation technique that measures flow through the smallest blood vessels (capillaries) and this information might be an important determinant of complications. In the future microcirculatory monitoring could guide therapy. This study will look at the microcirculation before, during and after liver resection surgery to see if it provides clinically relevant information.

Who can participate?
Patients undergoing elective liver resection surgery.

What does the study involve?
Taking part in this study will not affect your care in any way. It is simply gathering further information which may eventually help us tailor our practice better for individual patients. Before your operation we will place a very small camera-type device under your tongue to collect information on blood flow in the small blood vessels in the tongue. We will repeat these measurements after you have been put to sleep but before the operation has started, during surgery when the liver is first exposed, at the time they have finished removing part of the liver, when you first arrive at intensive care, and later on in intensive care after you have received some fluids through a drip. We will also place this device on your liver during the surgery to measure the blood flow in the small vessels in the liver when it is first exposed and again after part of the liver has been removed. During surgery the camera will be covered in a sterile plastic sheath to ensure there is no risk of introducing infection. This will be the same method we would use to prevent infection when introducing instruments for keyhole surgery. During some of these measurements you will be awake and the sensation would be similar to a thermometer being placed under the tongue. This will not be there continuously but for a period of minutes to gain readings of the blood flow. You will be unaware of measurements taken during the surgery as you will be anaesthetised (asleep).

What are the possible benefits and risks of participating?
There will be no direct benefit or risk to you personally in this study. We will collect information enabling us to better understand blood flow in the small blood vessels (capillaries) of patients undergoing liver resection and whether this relates to patient outcomes. The information gained from this study could provide the basis for future studies looking at different treatments for patients based on the blood flow in their small blood vessels, which may improve patient care. The camera-type device used may be slightly uncomfortable when placed under the tongue, similar to a thermometer being placed under the tongue. It will not be painful and you can choose to withdraw from the study at any point. All your care relating to the surgery will be carried out identically whether you participate in the study or not.

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?
From December 2014 to December 2015

Who is funding the study?
Surrey Peri-operative Anaesthetic Critical care colaboraive Research group (SPACeR) (UK)

Who is the main contact?
Dr Ben Creagh-Brown

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Microvascular monitoring during liver resection surgery - a pilot prospective observational cohort study

Acronym
MicroHepFlow

Study objectives
Microvascular perfusion is impaired following macrohaemodynamic stabilisation after liver resection surgery, compared to microvascular perfusion measured pre-operatively.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Proportionate Review Sub-committee of the NRES Committee North East - Tyne & Wear South, 23/09/2014, ref: 14/NE/1150

Study design
Prospective observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

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
Liver surgery, microcirculatory monitoring

Interventions
Patients enrolled into the study will have imaging of the blood flow in the small blood vessels in their tongue. This will be measured by placing a camera underneath the tongue, similar to positioning a thermometer under the tongue to measure temperature. It will take approximately 10-15 minutes to position the camera and obtain the images. Images will be recorded before surgery, after you have been put to sleep but before the operation has started, during surgery when the liver is first exposed, at the time they have finished removing part of the liver, when you first arrive at intensive care, and later on in intensive care after you have received some fluids through a drip. We anticipate this to take a total of 60 to 90 minutes where the camera is in place. Half of these measurements (30-45 minutes divided into three separate 10-15 minute episodes) will be taken whilst you are awake and the rest you will be unaware of as you will be asleep during your surgery. In addition to this two measurements will be taken of blood flow in the small blood vessels of the liver, both of which you will be unaware of as you will be asleep. All patient data will be anonymised and entered onto a secure patient database.

Intervention Type
Other

Primary outcome measure
The primary analysis will compare the proportion of perfused vessels (PPV, %) for small (<20 μm) vessels at two time points: A (pre-anaesthetic); and during the liver resection surgery when the patient is maximally 'dessicated' (time B) using paired T-test or Wilcoxon non-parametric method if assumptions of normality are not met. Two-sided (5%) alpha level will be used to assess significant difference.

Secondary outcome measures
1. Another analysis will compare the paired PPV at times A and C (pre-anaesthetic and after GDFT, respectively) using the same paired T-test or Wilcoxon non-parametric method
2. The patients' PPV at all time (A, B and C) points will be compared between groups (with and without complications; with less than, or greater than, the median peak lactate in the first 24 hours; does/does not require vasoactive therapy for greater than 24 hours on ICU) using two-way repeated measures ANOVA for each variable separately or appropriate non-parametric method. Post hoc test will use Bonferroni method to adjust for multiple testing
3. To assess the relationship between automated Microscan measurements from sublingual and hepatic measurements taken during the intra-operative period Pearson's correlation coefficient or Spearman's rank correlation will be used as appropriate

Overall study start date
01/12/2014

Completion date
01/12/2015

Eligibility

Key inclusion criteria
1. At least 18 years of age
2. Elective (planned) liver resection surgery
3. Provides informed consent to participate in surgery

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Glossectomy (previous surgery to remove part or all of the tongue)
2. Glossitis (inflammation of the tongue)
3. Lack of mental capacity

Date of first enrolment
01/12/2014

Date of final enrolment
01/12/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Intensive Care Unit
Royal Surrey County Hospital
Guildford
United Kingdom
GU2 7XX

Sponsor information

Organisation
Royal Surrey County Hospital NHS Foundation Trust

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/050bd8661

Funder(s)

Funder type
Research organisation

Funder Name
Surrey Peri-operative Anaesthetic Critical care collaboraive Research group (SPACeR)

Results and Publications

Publication and dissemination plan
The trialists plan to publish the results in a peer-reviewed journal in addition to presenting results as either an oral presentation or poster at national +/- international meetings.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

HRA research summary	28/06/2023	No	No