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Image guidance with image overlay for laparoscopic surgery

Submission date 05/11/2014	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 14/11/2014	**Overall study status** Completed	
Last Edited 09/07/2020	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims
During keyhole liver surgery (laparoscopic liver resection), some internal structures may be difficult to distinguish from one another or difficult to see as they are deep within the organ. An example is identifying the vessels in the liver which lie deep within the liver and are not visible on the surface of the liver, which is the part seen by the surgeon. Clear identification of structures will help avoid injury to important structures which will benefit the patient. One way of achieving this is to superimpose the images obtained by scans (which can easily distinguish different structures) prior to the operation (preoperative images) on to video laparoscopic images obtained during the actual operation so that the surgeon can identify the tissue. However, the main drawback of this is that the organs can be deformed by pushing and pulling of the organs, normal breathing movements of the patient, and insufflation of gas during laparoscopy, making it difficult to superimpose the preoperative images on to the liver images (as the preoperative images are captured while the person is holding their breath without traction or pressure from gas). The aim of this study is to investigate whether an integrated system using tracking devices, image capturing devices, and a computerised algorithm that aligns the computer model and in-situ liver can facilitate the overlap of the images. Other than the computerised algorithm, all the other components have been certified for clinical application and will be used as intended.

Who can participate?
Patients scheduled to undergo laparoscopic liver resection or staging laparoscopy.

What does the study involve?
While the participants will undergo staging laparoscopy or laparoscopic liver resection the operation will not be altered in any form for the purpose of the study. Equipment required to track the movement of surgical instruments will be used in theatre and two to three researcher's team members will be present in theatre during the surgery. A video of the operation will be recorded via the laparoscopic camera. No information that could identify the patient will be recorded for the study. All observations and measurements will take place while the patient is under general anaesthetic and therefore his/her pre- and post-operative care will not be affected.

What are the possible benefits and risks of participating?
The risk to the patient is minimal to non-existent. The technology required to record observations will remain external to the patient's body and will not have any contact with it at any point. The study results could have benefits for the wider community of patients undergoing laparoscopic surgery in the future but will not immediately benefit participating patients. We aim to develop an image guidance system that will improve outcomes in laparoscopic liver surgery by reducing the risk of injury to vulnerable structures and increasing the number of patients eligible for laparoscopic liver resection.

Where is the study run from?
Royal Free Hospital (UK).

When is the study starting and how long is it expected to run for?
October 2014 to March 2021

Who is funding the study?
Department of Health and Wellcome Trust Health Innovation Challenge Fund (UK).

Who is the main contact?
Mr Crispin Schneider

Contact information

Type(s)
Scientific

Contact name
Mr Crispin Schneider

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

17183

Study information

Scientific Title
Image guidance with image overlay for laparoscopic surgery: an observational case-controlled study

Study objectives
During keyhole liver operation (laparoscopic liver resection), some internal structures may be difficult to distinguish from one another or difficult to see as they are deep within the organ. An example is identifying the vessels in the liver (which lie deep within the liver and are not visible on the surface of the liver, which is the part seen by the surgeon). Clear identification of structures will help avoid injury to important structures which will benefit the patient. One way of achieving this is to superimpose the images obtained by scans (which can easily distinguish different structures) prior to the operation (preoperative images) on to video laparoscopic images obtained during actual operation so that the surgeon can identify the tissue.

The aim of this research is to investigate whether an integrated system using tracking devices, image capturing devices, and a computerised algorithm can facilitate the overlap of the images. Other than the computerised algorithm, all the other components have been certified for clinical application and will be used as intended.

More details can be found here: http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=17183

On 11/09/2015 the following changes were made to the trial record:
1. The overall trial end date was changed from 30/09/2015 to 30/04/2016.
2. The target number of participants was changed from 6 to 10.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. NRES Committee London - Stanmore, 19/09/2014, ref: 14/LO/1264
2. NRES Committee London - Stanmore, 25/06/2014, ref: 10/H0720/87

Study design
Non-randomised; Observational; Design type: Case-controlled study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)

Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Laparoscopic liver surgery

Interventions
Current interventions as of 11/09/2015:
The aim of the study is to use preoperative CT scans of the patients to create a computerised 3D model of the liver that depicts the position of blood vessels and tumour lesions. During surgery, this 3D model will then be overlaid onto the video-laparoscopic image of the patient's liver to aid the surgeon in localising tumours, decide on the optimal plane of resection and avoid inadvertent injury to blood vessels and other vulnerable structures.

Patients undergoing staging laparoscopy or laparoscopic liver resection will be evaluated. To achieve an accurate overlay of 3D model and in-situ liver, tracking of the liver surface and surgical instruments will be performed. The overlay of the 3D computer model onto the video-laparoscopic feed will be displayed on screen but not shown to the surgeon as to not influence his decision-making process at this stage of the study. The overall accuracy (in millimetres) of overlaying the computerised 3D model of the patient's liver onto a video laparoscopic feed will be measured as the primary outcome. Patients will be followed up postoperatively for three months in total.

Previous interventions:
The aim of the study is to use preoperative CT scans of the patients to create a computerised 3D model of the liver that depicts the position of blood vessels and tumour lesions. During surgery, this 3D model will then be overlaid onto the video-laparoscopic image of the patient's liver to aid the surgeon in localising tumours, decide on the optimal plane of resection and avoid inadvertent injury to blood vessels and other vulnerable structures.

The methodological approach is briefly outlined below. Initially six patients will have CT scans performed in theatre while undergoing a staging laparoscopy. This will obtain information about the liver's deformation behaviour during establishment of pneumoperitoneum (raised intra-abdominal pressure). Data from these CT scans will then be implemented into the computer model to optimise the soft tissue deformation algorithm.

In the next step six patients undergoing laparoscopic liver resection will be evaluated. To measure the real-time deformation that the liver undergoes during surgery, tracking of the liver surface and surgical instruments will be performed. Anatomical landmarks such as vessel anatomy will be obtained using laparoscopic ultrasound to increase the accuracy and adaptability of the displayed liver model. The overlay of the 3D computer model onto the video-laparoscopic feed will be displayed on screen in real-time but not shown to the surgeon as to not influence his decision-making process at this stage of the study.

The overall accuracy of overlaying the computerised 3D model of the patient's liver onto a live video laparoscopic feed will be measured as the primary outcome. Accuracy will be recorded in millimetres and the data collection will take place for the whole duration of surgery. Patients will be followed up postoperatively for three months in total.

Intervention Type

Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Overall accuracy of image overlay between projected image and video laparoscopic image;
Timepoint(s): Accuracy data will be processed and recorded during surgery

Secondary outcome measures
1. Intra-operative and post-operative complications
2. Length of hospital stay

Overall study start date
01/10/2014

Completion date
31/03/2021

Eligibility

Key inclusion criteria
Current inclusion criteria as of 11/09/2015:
1. Any patient scheduled to undergo staging laparoscopy or laparoscopic liver surgery at the Royal Free Hospital will be eligible for enrolment in the study
2. There are no gender restrictions and the recruitment age is 18 to 80 years old

Previous inclusion criteria:
1. For the first step any patient requiring a laparoscopy for the preoperative staging of abdominal malignancy can be included
2. For the subsequent step any patient scheduled to undergo laparoscopic liver surgery at the Royal Free Hospital will be eligible for enrolment in the study
3. There are no gender restrictions and the recruitment age is 18 to 80 years old

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants

Planned Sample Size: 10; UK Sample Size: 10

Key exclusion criteria
1. Unable to understand English
2. Unable to provide consent themselves

Date of first enrolment
04/12/2014

Date of final enrolment
31/12/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Free Hospital
London
United Kingdom
NW3 2QG

Sponsor information

Organisation
Royal Free Hampstead NHS Trust (UK)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04rtdp853

Funder(s)

Funder type
Charity

Funder Name
Department of Health and Wellcome Trust Health Innovation Challenge Fund (UK); Grant Codes: HICF-T4-317

Results and Publications

Publication and dissemination plan
To be confirmed at later date

Intention to publish date
31/10/2021

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository

Study outputs

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