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Automated 3D overlay for X-ray guided surgery

Submission date
08/01/2015

Recruitment status
No longer recruiting

Registration date
16/01/2015

Overall study status
Completed

Last Edited
24/07/2020

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
For some types of keyhole surgery and procedures, it is not possible to use camera technology and X-rays are used for guidance instead. While X-rays are good at showing the position of bones and surgical instruments, they do not show soft tissues well and they produce flat (2D) pictures. On the other hand, CT scans show soft tissues and can produce solid (3D) images but they are not very good for guiding procedures because of the amount of radiation. This study is testing a new technology that uses high-powered computing to match the X-ray pictures (that doctor will use to guide an operation) to an earlier CT scan. Accurate matching of the X-rays to the CT scan means that the doctor can see 3D images of parts of the body that can't otherwise be seen with just X-rays. This study tests a new technology that will help doctors see more clearly during X-ray guided surgery. It is hoped that this will reduce the amount of X-rays needed during surgery and lead to better outcomes for patients in future.

Who can participate?
Patients aged 18 or over who are booked for an X-ray guided intervention in an anatomic zone covered by the technology

What does the study involve?
The doctors performing the procedures use the new 3D guidance technique in addition to the standard X-ray technique. The accuracy and reliability of the new technology is analysed to check if it is safe and performs as expected. The amount of X-ray (radiation) exposure, the length of operation and the dose of iodinated contrast (a potentially harmful substance widely used to help these procedures) are recorded.

What are the possible benefits and risks of participating?
The doctor may be able to see the anatomy inside the body a bit more clearly, and participants may have a quicker operation or procedure and be exposed to fewer potentially harmful X-rays. It is possible that the 3D overlay system may disagree with the standard X-ray technique and a double-check of position is needed, in which case participants may be exposed to more X-rays than normal.

Where is the study run from?
St Thomas's Hospital (UK)

When is the study starting and how long is it expected to run for?
November 2014 to March 2015

Who is funding the study?
Cydar Limited and Technology Strategy Board (UK)

Who is the main contact?
Mr Tom Carrell

Study website
http://www.cydar.co.uk/

Contact information

Type(s)
Scientific

Contact name
Mr Tom Carrell

Contact details
St Thomas's Hospital
249 Westminster Bridge Road
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
17937

Study information

Scientific Title
Cloud high-performance computing for 3D overlay in X-ray guided surgery: an observational case-controlled study

Study objectives
CT scans are a common diagnostic test that contain 3D information and show soft tissues, but they are not useful for live guidance due to high radiation dose. Instead, low-dose X-ray videofluoroscopy guidance is used to guide many types of keyhole surgery. But while X-rays are good at showing bones and the position of surgical instruments, they do not show soft tissues well and they produce flat (2D) images that superimpose all the 3D anatomical features. One

way to improve clinicians' perception of 3D anatomy and soft tissue is to accurately overlay selected information from a preoperative CT scan onto the live X-ray image, creating a '3D roadmap'. The research team from King's College London and Guy's and St Thomas' NHS Trust have developed an automated 3D roadmap software technology for use in X-ray guided keyhole surgical procedures. This has been tested and validated in more than 130 operations over the last 5 years (IRAS 09/H/0707/64). The technology uses software algorithms to detect anatomical information present in live X-ray images and match ('register') them to the preoperative CT scan in order to determine the patient's exact position. This match then allows 3D information from the preoperative CT scn to be overlaid on the live X-ray. The system requires high computing power to work quickly. Cydar Ltd is a spinout company from King's College London and Guy's and St Thomas' NHS Trust, taking this technology and building a prototype system, Cydar RTRS1.0, that uses the power of cloud high-performance computing to deliver a fast, clinically useful system. The next step in the development of this technology is to test the RTRS1.0 cloud high-performance computing prototype to test the safety, performance, usability and clinical benefit with a view to finalising system design and regulatory approval.

Ethics approval required
Old ethics approval format

Ethics approval(s)
14/EE/1143; First MREC approval date 10/10/2014

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)
Treatment

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

Health condition(s) or problem(s) studied
Topic: Surgery; Subtopic: Surgery; Disease: All Surgery

Interventions
Automated 3D overlay. Software will generate overlays of 3D anatomy from a pre-operative CT scan, registered to intraoperative XR fluoroscopy images with the intent of enhancing the interventional clinicians' perception of 3D anatomy.

Intervention Type
Device

Primary outcome measure
Accuracy and robustness; Timepoint(s): Real-time acquisition of image registration data during X-ray guided procedure for analysis

Secondary outcome measures
Measured once during the X-ray guided intervention:
1. Procedure time
2. Radiation dose
3. Iodinated contrast dose

Overall study start date
24/11/2014

Completion date
31/03/2015

Eligibility

Key inclusion criteria
1. Willing and able to give informed consent
2. Aged 18 or over
3. Booked for an X-ray guided intervention in an anatomic zone covered by the technology (currently paravertebral: e.g. aortoiliac, spinal, retroperitoneal, pelvic)
4. Have had a preoperative CT scan
5. Able (in the investigator's opinion) and willing to comply with the study requirements

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 300; UK Sample Size: 300; Description: comprised of 60 patients estimated per 5 sites

Key exclusion criteria
1. Female participants who are pregnant or planning pregnancy during the course of the study
2. Any other significant disease or disorder which, in the opinion of the Investigator, may either put the participants at risk because of participation in the study, or may influence the result of the study, or the participant’s ability to participate in the study
3. Participants who have participated in another research study involving an investigational product in the past 12 weeks

Date of first enrolment
02/12/2014

Date of final enrolment
31/03/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St Thomas's Hospital
249 Westminster Bridge Road
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
Guy's and St Thomas' NHS Foundation Trust

Sponsor details
c/o Balathas Thirugnanabalan
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Industry

Funder Name
Cydar Limited (UK)

Funder Name
Technology Strategy Board

Alternative Name(s)
TSB

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The results have been presented at international meetings (VEITH 2016, ICI 2017) but have not otherwise been published.

Intention to publish date

Individual participant data (IPD) sharing plan
Electronic imaging data from CT scans and X-ray fluoroscopy are stored in the Cydar Vault, an ISO27001 certified data repository, as pseudonymised files. Patient identifier keys for the pseudonyms are stored in a separate Cydar Vault container. Consent from all 109 participants was obtained. Personal Health Information is not processed by Cydar.

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