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Pilot study comparing needle placement for Irreversible Electroporation (IRE) using CT navigation versus conventional CT-guidance

Submission date
24/04/2016

Recruitment status
No longer recruiting

Registration date
09/05/2016

Overall study status
Completed

Last Edited
14/06/2023

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Irreversible Electroporation (IRE) is a novel method for focused treatment of liver tumors. IRE is a soft tissue ablation technique (that is, a technique used to remove soft body tissues, including tumors) using ultra-short but strong electrical fields to create permanent and hence lethal nanopores (tiny holes) in the cell membrane resulting in cell death. IRE ablation requires the placement of two or more applicator electrodes between which the electrical fields are applied. In order to achieve successful ablation, parallel needle placement at a pre-defined distance is required. Needles are placed under image guidance using ultrasound or computer tomography as imaging methods. Since these methods display one image plane at a time, the realization of multiple parallel needle placements can be challenging. Several attempts may be required to achieve the required geometrical configuration of the needle with respect to other needles and as well as in relation to the anatomical target. Navigation technology for interventional radiology supports IRE treatments by providing comprehensive planning of needle configurations using 3D image data and by supporting needle placement through guidance functionality. This study aims to investigate the potential benefits of CT-navigated stereotactic IRE needle placement compared to non-navigated conventional IRE.

Who can participate?
Adult patients (aged at least 18) about to be treated with IRE for liver tumors.

What does the study involve?
Participants are split into two groups. Those in group 1 undergo the CT-navigated stereotactic IRE. Those in group 2 are treated by conventional IRE using manual needle placement. The time taken for accurate IRE needle placement for all patients is assessed, along with overall time of procedure and the radiation dose required for the IRE session.

What are the possible benefits and risks of participating?
Potential benefits for patients undergoing stereotactic IRE might be faster intervention times. No additional risks or side effects are expected .

Where is the study run from?
Department of Radiology at the University Hospital Regensburg (Germany)

Who is the main contact?
Dr Lukas Beyer

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
1.0

Study information

Scientific Title
Pilot study comparing needle placement for Irreversible Electroporation (IRE) using CT navigation versus conventional CT-guidance: a non-randomized prospective two-arm study

Study objectives
CT-navigation allows for faster placement of IRE needle applicators with a reduced number of pre-placements and control scans.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University Hospital Regensburg (02/2015).

Primary study design
Interventional

Study design
Non-randomized prospective two-arm study.

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Liver cancer

Interventions
Irreversible Electroporation (IRE) is a novel method for focused treatment of liver tumors. IRE is a soft tissue ablation technique using ultra short but strong electrical fields to create permanent and hence lethal nanopores in the cell membrane, to disrupt the cellular homeostasis. The resulting cell death results from apoptosis and not necrosis as in all other thermal or radiation based ablation techniques. IRE is used for non-resectable liver tumors in the vicinity of vessels (due to the its selectivity for tumor tissue while preserving vessel structures).

IRE ablation requires the placement of two or more applicator electrodes between which the electrical fields are applied. In order to achieve successful ablation, parallel needle placement at a pre-defined distance is required. Needles are placed under image guidance using ultrasound or computer tomography as imaging methods. As these methods are displaying one image plane at a time, the realization of multiple needle placements can be challenging and can require several attempts until the required geometrical configuration of the needle with respect to other needles and also to the anatomical target is achieved.
Navigation technology for interventional radiology supports IRE treatments by providing comprehensive planning of needle configurations using 3D image data and by supporting needle placement through guidance functionality.

This study aims to investigate the potential benefits of CT-navigated IRE needle placement compared to conventional non-navigated techniques.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Not provided at time of registration

Primary outcome(s)
Time required for the placement of IRE needles (measured from the time of the first CT scan to the start of the ablation).

Key secondary outcome(s)
1. Accuracy of IRE needle placement compared to a patient-specific ablation strategy (accuracy is measured as distance to the target point, distance between needles, angles between needles)
2. Overall procedure time
3. Number of lesions treated per patient
4. Number of needle replacements
5. Number of control scans
6. Radiation dose

Completion date
01/03/2016

Eligibility

Key inclusion criteria
1. Patients must be scheduled for CT guided percutaneous IRE in the liver
2. Written informed consent
3. Male patients and non-pregnant, non-lactating females aged ≥18 years of age (negative serum /urine pregnancy test result at screening)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Any condition which, in the judgment of the clinical investigator or his designee, might increase the risk to the subject or decrease the chance of obtaining satisfactory data to achieve the objectives of the study
2. A mental condition rendering the patient unable to provide informed consent
3. Patients with hereditary haematological / coagulation disorders unrelated to their liver disease.
4. Patients who are currently (within the last 30 days prior to surgery) participating in another clinical trial with any investigational drug or device
5. Patients undergoing liver surgery for the purpose of receiving a liver transplant or for liver trauma
6. Patients with established renal insufficiency (Creatinine >2.5 mg/dl), or a condition requiring hemodialysis

Date of first enrolment
01/07/2015

Date of final enrolment
31/01/2016

Locations

Countries of recruitment
Germany

Study participating centre
University Hospital Regensburg
Germany
93053

Sponsor information

Organisation
University Hospital Regensburg

ROR
https://ror.org/01226dv09

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Universitätsklinikum Regensburg

Alternative Name(s)
University Hospital Regensburg, UKR

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Germany

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		11/08/2016	14/06/2023	Yes	No
Dataset			14/06/2023	No	No
Participant information sheet			25/05/2016	No	Yes