

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

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<b>Registration date</b> 09/05/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 14/06/2023	<b>Condition category</b> Cancer	<input checked="" type="checkbox"/> 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

Dr Lukas Beyer

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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).

### Study design

Non-randomized prospective two-arm study.

**Primary study design**

Interventional

**Secondary study design**

Non randomised study

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

See additional files

**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 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 measure**

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

### **Secondary outcome measures**

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

### **Overall study start date**

01/07/2015

### **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  $\geq 18$  years of age (negative serum /urine pregnancy test result at screening)

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

### **Target number of participants**

20

### **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

**Sponsor details**

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**Sponsor type**

Hospital/treatment centre

**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

**Publication and dissemination plan****Intention to publish date**

01/03/2017

**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?
<a href="#">Participant information sheet</a>			25/05/2016	No	Yes
<a href="#">Dataset</a>			14/06/2023	No	No
<a href="#">Results article</a>		11/08/2016	14/06/2023	Yes	No