Clinical Intervention Modelling, Planning and Proof for Ablation Cancer Treatment

Published: 27-10-2015
Last updated: 19-04-2024

Comparison of the size and shape of the ablation zone of liver tumors with the simulation results of the ClInicIMPPACT software environment

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON42524

Source
ToetsingOnline

Brief title
ClinicIMPPACT

Condition

- Hepatobiliary neoplasms malignant and unspecified

Synonym
Colorectal liver metastases; Intestinal liver metastases

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: European Union Grant (Grant 610886)

Intervention

Keyword: Colorectal liver metastases, Hepatocellular carcinoma, Model, Radiofrequency

ablation

Outcome measures

Primary outcome

Comparison of the size and shape of the real ablation zone of liver tumors with

the simulation results of the ClinicIMPPACT software environment.

Secondary outcome

Evaluation of the workflow steps of the ClinicIMPPACT procedure.

Patient outcome (complications, tumor recurrence, survival)

Study description

Background summary

Patients with colorectal liver metastases are only suited for curative surgical intervention in 10-25% of cases. This is due to several criteria for resectability, such as, the size of the tumors, reserve liver parenchya, comorbidity and extent of livercirrosis.
In order to increase the number of patients, eligible for curative treatment, additional minimal invasive treatments have been developed, of which radiofrequency ablation (RFA) is the most researched and used. This treatment induced coagulation of the targeted lesion, using radiofrequency, and is currently commonly used in the world.
However, the problem with this procedure is the lack and inability of real-time monitoring during ablation. This can cause either under-treatment or over-treatment of the lesion.

This research aims to evaluate a simulation software, which is capable to estimate the expected ablation region. This can, in the future, be used to optimize the treatment.

Study objective

Comparison of the size and shape of the ablation zone of liver tumors with the simulation results of the ClInicIMPPACT software environment

Study design

15 patients will prospectively be included in this study. Patients will receive an additional perfusion CT scan combined with their standard 1 week before treatment planning CT scan. Following this CT, patients will receive ablation of their tumors using RFA and will receive standard care follow-up.

Study burden and risks

Patients undergo only one form of burden/ risk during this research:

During the standard preoperative planning CT, instead of a 4 phase CT liver, patients will receive an combined scan with perfusion and 4 phase.
The added amount of radiation is comparable to the normal preoperative planning CT.

Contacts

Public
Radboud Universitair Medisch Centrum

Geert Grootteplein 10
Nijmegen 6500 HB
NL
Scientific
Radboud Universitair Medisch Centrum

Geert Grootteplein 10
Nijmegen 6500 HB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Inclusion criteria:
• patients admitted for radiofrequency ablation (RFA) of a liver tumor (maximum tumor diameter of 3 cm, max. 3 lesions)
• age >= 18 years
• written informed consent

Exclusion criteria

Exclusion criteria
• known anaphylactic reaction against iodine / contrast agent
• malfunction of the kidney (non treatable renal insufficiency; MDRD< 25)
• thyroid disease (non treatable hyperthyreosis)
• Splenectomy
• pregnant or nursing women
• concurrent participation in other interventional trials

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-11-2015
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO Date:	27-10-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL54334.091.15