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Treatment of primary and secondary liver tumors with an hepatic ablation cool-wet radiofrequency system.

Submission date	Recruitment status	[_] Prospectively registered
13/04/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/06/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/07/2023	Cancer	

Plain English summary of protocol

Background and study aims
Radiofrequency ablation is a cancer treatment that uses heat made by radio waves to kill cancer cells. Radiofrequency is a type of electrical energy that heats up solid tumours and kills it. The aim of this study is to compare a new method we have developed for ablating liver tumours, the hepatic "cool-wet" radiofrequency ablation system with other methods already available. The study also investigates how safe the method is to use (phase 1 of the study) and how effective a treatment it is (phase 2).

Who can participate?
Adults (aged at least 18) with liver cancer (hepatocellular carcinoma and macrotrabecular with <3 lesions of 1.5-4 cm diameter)

What does the study involve?
There are two phases to the study. In phase 1, the safety of “cool-wet” radiofrequency system is tested. In phase 2, participants are randomly allocated into one of two groups. Those in group 1 undergo a conventional hepatic (liver) ablation technique. Those in group 2 are given the new “cool-wet” hepatic radiofrequency ablation system. The clinical outcomes of the two groups of participants are then compared in terms of whether the treated cancer reoccurred.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
The Hospital del Mar (Spain)

When is the study starting and how long is it expected to run for?
January 2012 to June 2020

Who is funding the study?
Health Research Fund (Fondo de Investigación Sanitaria) (Spain)

Who is the main contact?
Dr Rita Quesada
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
438/13/EC

Study information

Scientific Title
Treatment of primary and secondary liver tumors with an hepatic ablation cool-wet radiofrequency system: an interventional single-centre study.

Acronym
GNOMON

Study objectives
Current study hypothesis as of 17/06/2020:
1. Assess the safety of the radio-frequency ablation with the new device ("cool-wet system" to treat hepatocellular carcinoma and liver metastases between 1.5 - 4 cm of diameter.
2. Verify if the new radio-frequency method is at least as effective than the conventional method in terms of technical success of the lesion and overall survival. The conventional method considers the current technique performed by interventional radiologists and surgeons of the

hospital (microwaves) for any of the possible ways of application (percutaneous, laparoscopic or open surgery).

Previous study hypothesis:
1. Assess the safety of the radio-frequency ablation with the new device ("cool-wet system" to treat hepatocellular carcinoma and liver metastases between 1.5 - 4 cm of diameter.
2. Verify if the new radio-frequency method is at least as effective than the conventional method in terms of lower recurrence and total ablation of the lesion (single puncture). The conventional method considers the current technique performed by interventional radiologists and surgeons of the hospital (ablation method cool-tip and microwaves) for any of the possible ways of application (percutaneous, laparoscopic or open surgery).

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethical Committee of Clinical Research of the Hospital del Mar, 27/06/2012, ref: 2012/4776/I
2. Agencia Española del Medicamento y Producto Sanitario, 10/06/2013, ref: 438/13/EC

Study design
Interventional prospective randomized parallel-group single-blinded study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

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
Hepatocellular carcinoma and liver metastases between 1.5 - 4 cm of diameter

Interventions
Current interventions as of 15/06/2020:
Radio-frequency ablation with a "Cool-wet" radio-frequency system
Phase II: Randomized, parallel-group single-blind study
1. Group MWA: Conventional hepatic ablation technique (control group). The method of ablation control is based on microwaves (AMICA) (n=41 patients)
2. Group RFA: New "cool-wet" hepatic radio-frequency ablation system . (n=41 patients)

Previous interventions:
Radio-frequency ablation with a "Cool-wet" radio-frequency system

1. Phase I: Safety pilot study based on 20 patients. There is no control group
2. Phase II: Randomized, parallel-group single-blind study
2.1. Group 1: Conventional hepatic ablation technique (control group). The method of ablation control is based on microwaves (AMICA). It considers 55 patients
2.2. Group 2: New "cool-wet" hepatic radio-frequency ablation system previously described in Phase I. 55 patients

Intervention Type
Procedure/Surgery

Primary outcome measure
Current primary outcome measures as of 15/06/2020:
1. Technical success evaluated as a complete tumor coverage by the ablation zone at 1-month follow-up
2. Local tumour progression after 2 years of follow-up, measured as complete tumor coverage by the ablation zone and the appearance of any tumor focus in contact with ablation zone after 2-years follow-up

Previous primary outcome measures:
1. HLR (Hepatic local recurrence): Characterized by a partial response (PR) or disease progression (DP) of the treated target lesion according to RECIST 1.1 VA. in the abdominal CT or MRI at 6 months (maximum tolerance 50 days) and then every 6 months until 5 years. The maximum cutting thickness to evaluated this is 5 mm
2. MDA (Minimum Diameter Ablation): Defined as the smallest diameter of a single ablation measured by an abdominal CT or MRI at 6-months of the procedure. When they have been treated more than one target lesion, the smallest diameter will be considered

Secondary outcome measures
Current secondary outcome measures as of 17/06/2020:
1. Safety: all treatment-related complications classified according to the Society of Interventional Radiology guidelines by treated tumor basis taking into account the highest grade. Complications recorded during the total follow-up of the patients.
2. Overall survival (OS) measured as the mean survival expressed in months per each group of treatment
3. Short to long diameter ratio (SLR) of the ablation measured from the TAC performed 1 month after the ablation
4. Sphericity ratio (SR) measured as the largest diameter to average of the two remaining diameters of the ablation zone. Ratio close to 1 implies more spherical shape, measured from the TAC performed 1 month after the ablation.
5. Surface area of the coagulation zone measured in cm^2 from the reconstruction of the coagulation zone (1 month after the ablation)
6. Coefficient of variation (CV) as a measure for reproducibility expressed in % and measured from the reconstruction of the coagulation zone (1 month after the ablation)

Previous secondary outcome measures:
1. Maximum diameter of the ablation (anteroposterior, transverse and craniocaudal)
2. Mean volume of the ablation, measured by digital reconstruction from CT or MRI after a month of PO using appropriate image software

Overall study start date
01/01/2012

Completion date
01/06/2020

Eligibility

Key inclusion criteria
1. Nodules suggestive of HCC or liver metastases from any source as abdominal CT, MRI or biopsy. The initial imaging test (CT or MRI) must not be older than 30 days (50 days maximum tolerance).
2. Considered unresectable hepatic nodules in multidisciplinary and capable local treatment session
3. Number of nodes: between 1 and 3
4. Size of the nodules: between 1.5 and 4 cm
5. Percutaneous, laparoscopic or open surgical access.
6. Signature of informed consent
7. Aged at least 18

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
130

Total final enrolment
102

Key exclusion criteria
1. Higher than third level of Anesthetic risk measured by the classification of the American Association anesthesia (ASA IV)
2. Carrier of a cardiac pacemaker
3. Thrombocytopenia <50,000 / mL
4. Suspicion of thrombosis portal by presence of tumor
5. Child C and grading of hepatic failure
6. Previous biliodigestive anatomosis
7. Hepatic subcapsular nodule

Date of first enrolment
01/06/2015

Date of final enrolment
01/04/2020

Locations

Countries of recruitment
Spain

Study participating centre
Hospital del Mar
Spain
-

Sponsor information

Organisation
Parc de Salut Mar- Hospital del Mar

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03a8gac78

Funder(s)

Funder type
Government

Funder Name
Health Research Fund (Fondo de Investigación Sanitaria) (FIS PI12/00799)

Results and Publications

Publication and dissemination plan
The trialists intend to publish at least two papers, one after the first Phase I and another after Phase II. They have already finished the first phase of the study and are currently analyzing the results. They plan to publish these as soon as they have them. The second publication will depend on the inclusion of patients.

Intention to publish date
30/06/2020

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be available upon request from Dr Rita Quesada (rquesada@imim.es). Part of the database will become available for 2 years to medical researchers. The principal investigator of the study will evaluate the request and will decide which data can be shared.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		10/01/2022	10/07/2023	Yes	No