Transarterial RAdioembolization versus ChemoEmbolization for the treatment of HCC:
a multicenter randomized controlled trial

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The overall goal of this RCT is to compare the efficacy of 90Y-RE to TACE-DEB, for patients with intermediate stage HCC. Time to progression, overall survival, tumor response, adverse events, treatment related effect on total liver function, quality…

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

Summary

ID

NL-OMON38056

Source
ToetsingOnline

Brief title
TRACE trial

Condition

- Hepatobiliary neoplasms malignant and unspecified
- Hepatobiliary neoplasms malignant and unspecified

Synonym
hepatocellular carcinoma, liver cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: chemoembolization, hepatocellular carcinoma, radioembolization, Yttrium

Outcome measures

Primary outcome

Primary endpoint: time to progression.

Secondary outcome

Secondary endpoints: overall survival, tumor response, toxicities/adverse events, treatment related effect on total liver function, quality of life and treatment-related costs.

Study description

Background summary

Transarterial Yttrium-90 radioembolization (90Y-RE) is a novel technique for locoregional treatment of hepatocellular carcinoma (HCC). Although transarterial chemoembolization (TACE) is currently the standard of care for intermediate stage HCC patients, 90Y-RE is also used in the same group of patients, and it is unclear which treatment has a better efficacy. This randomized controlled trial (RCT) is designed to compare efficacy of 90Y-RE with TACE with drug eluting beads (DEB), for patients with intermediate stage HCC.

Study objective

The overall goal of this RCT is to compare the efficacy of 90Y-RE to TACE-DEB, for patients with intermediate stage HCC. Time to progression, overall survival, tumor response, adverse events, treatment related effect on total liver function, quality of life and treatment-related costs will be compared.

Study design

Multicenter randomised controlled intervention study.

Intervention

The intervention consists of either treatment with TACE-DEB, the standard of care, or 90Y-RE.

Study burden and risks

Patients with intermediate stage HCC are randomly assigned to either 90Y-RE or TACE-DEB. Both treatments are already performed in daily clinical practice and efficacy in large cohorts has been described, with a median survival of 16-20 months. Risks of both treatments are described in the literature and acceptable. Post procedural MRI is performed to investigate treatment effect (tumor response) at 1 months after baseline (the date of the first treatment T0), 3 months after baseline and at 3 monthly intervals thereafter for two years. This follow-up strategy is also implemented in usual medical practice. The patient is seen by the treating physician during regular visits to the outpatient clinic. Regular laboratory examination will be performed during these visits. Adverse events and toxicities are recorded and monitored for 6 months following last treatment. Patients are asked to fill out questionnaires for quality of life assessment before and after treatment. Questionnaires will be sent to the patients* home address by mail.

Contacts

Public
Universitair Medisch Centrum Utrecht

Postbus 85500
3508 GA Utrecht
NL
Scientific
Universitair Medisch Centrum Utrecht

Postbus 85500
3508 GA Utrecht
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Written informed consent
- Diagnosis HCC confirmed by typical appearance on imaging, i.e. hypervascular enhancing lesion in the arterial phase and contrast washout in the portal venous or delayed phase, or by cytohistological tissue sampling by biopsy in case of inconclusive imaging findings
- Intermediate stage HCC as defined by the BCLC criteria, i.e. >3 lesions >3cm in size, or 1 lesion >5cm in size (BCLC stage B)
- absence of extrahepatic disease
- Age >= 18 years
- Child-Pugh A-B7
- ECOG performance status (PST) 0-1

Exclusion criteria

- Inadequate bone marrow function (hemoglobulin <6.0 mmol/l, absolute neutrophil count < 1.5 x 109/l, platelet count <60 x 109/l)
- Inadequate liver function (bilirubin >45 µmol/l (or 2.6 mg/dl), albumin <28 g/l, AST/ALT >5x upper limit of normal (ULN)
- Inadequate renal function (creatinine >1.5x ULN)
- Compromised biliary system
- Hypersensivity to doxorubicin
- Pregnancy or breast feeding
- >50% of liver involvement
- main portal vein (right, left or common trunk) thrombosis
- 99mTc-MAA-scintigraphy shows limited MAA uptake (photopenic lesion)
- Lung shunting fraction >20%
- Patients who are declared incompetent or suffering from psychic disorders that make a comprehensive judgement impossible, such as psychosis
- Previous local treatment of study target lesion(s)
- Allergy for i.v. contrast used (Visipaque®)
- Life expectancy <3 months or otherwise impossible follow-up
- Patients in whom hepatic artery catheterization is contraindicated; such as patients with

vascular abnormalities or bleeding diathesis (indicated by a PT >6 seconds over control)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-11-2011
Enrollment:	90
Type:	Actual

Medical products/devices used

Generic name:	TheraSphere
Registration:	Yes - CE intended use
Product type:	Medicine
Brand name:	DC Bead
Generic name:	DC Bead
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	23-09-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO Date:	01-11-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	21-02-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	12-03-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	17-09-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
EudraCT	EUCTR2011-001794-85-NL
CCMO	NL33784.041.11