Transarterial Chemoembolization with Drug-Eluting Beads Loaded with Doxorubicin for the Treatment of Metastatic Breast Cancer to the Liver: a pilot study

Published: 13-06-2012
Last updated: 26-04-2024

To study the safety, feasibility ,t oxicity , tolerance and respons rate (RECIST-criteria) of the intra-arterial treatment with Doxirubicin -loaded Beads (DEBDOX) in patients with liver dominant metastasized breast cancer.

Ethical review	Approved WMO
Status	Pending
Health condition type	Metastases
Study type	Interventional

Summary

ID

NL-OMON37702

Source
ToetsingOnline

Brief title
Chemoembolization with Doxorubicin for Metastatic Breast Cancer .

Condition

- Metastases

Synonym
liver metastases breast cancer

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: uit academische budgetcomponent ziekenhuis

Intervention

Keyword: breast cancer, chemoembolization, doxorubicin, liver metastases

Outcome measures

Primary outcome

Technical feasibility of the treatment protocol, including: adequate pain

relief during the procedure, the loading of beads, angiographic success and

procedure-related toxicity (defined as procedure related complications that

makes hospitalisation longer than 48 hours post-procedure necessary. Proportion

of patients completing scheduled treatment plan.

Secondary outcome

Response rate (according to RECIST), time to progression, and overall

survival .

Study description

Background summary

Transarterial chemoembolization and chemoperfusion are wellknown regional therapies that have been used in patients with hepatocellular carcinoma and liver metastases from colorectal carcinoma. Studies on the use of these strategies in patients with breast cancer are scarce, although these strategies have the ability to deliver highdose chemotherapy directly to the liver, with minimal systemic chemotherapy effects. In our department, we have limited experience with the interaarterial threatment of patient with liver metastases of breastcancer with mitomycin-C. The success rate of this treatment is limited.
Drug eluting bead TACE is a novel drug delivery system that combines the local

embolization of vasculature with slow release of chemotherapy into tissue. Beads are composed of biocompatible polymers such as polyvinyl alcohol (PVA). They occlude vasculature , causing embolization, and the chemotherapy is delivered locally The aim of the present study is to evaluate the efficacy of hepatic arterial doxorubicin therapy in MBC.

Study objective

To study the safety, feasibility ,t oxicity , tolerance and respons rate (RECIST-criteria) of the intra-arterial treatment with Doxirubicin -loaded Beads (DEBDOX) in patients with liver dominant metastasized breast cancer.

Study design

A prospective, non-controlled single-institution pilot study.

Intervention

The treatment is hepatic intra-arterial therapy with doxorubicin loaded DC Bead .

DC Bead® are hydrogel-embolic, drug-eluting beads that are precisely calibrated and made of polyvinyl alcohol, are biocompatible, hydrophilic and non-resorbable. During a 2-hour loading period 150 mg of doxorubicin will be loaded on DC-beads in two bead vials .

Angiography procedure is performed (after placement of an epidural catheter for pain relief) by the interventional radiologist, during which selective celiac and superior mesenteric arteriography will be performed to evaluate the hepatic arterial anatomy. For tumors near the periphery of the liver, evaluation of potential extrahepatic supply to the tumors, such as the inferior phrenic, gastroepiploic, and internal mammary arteries, will be done.

The next step is to limit any type of extrahepatic perfusion of the treatment. The most common branches that will lead to extrahepatic disposition of treatment are the right gastric and gastroduodenal arteries, which are controlled either prior to infusion with coil embolization or with distal catheter placement.

DEBDOX will be mixed with non-ionic contrast (approximately 50/50 dilution) prior to injection.

For unilobar disease, a treatment cycle consists of two dosing schedules of 100-150 mg DEBDOX each .

For diffuse disease, four dosing schedules of 100-150 mg DEBDOX (alternating

in both hepatic lobes, first into either the right or left artery, depending on the bulk of disease) is performed, with a 2- to 4-week interval, depending on toxicity.

A repeat CT-scan will be performed every 3 months from the initial first treatment cycle to evaluate response as well as planned retreatment .

Study burden and risks

Risk of CT: hypersensitivity to iodinated contrast medium, contrastnefropathy in patient with increased risk. These risk are equal to the risk of any other patient undergoing CT-scans

Risk of angiograpy: bleeding at the puncture site (0-5%), development of pseudoaneurysm (very rare), dissection (very rare).

Risk of embolization: postprocedural pain (often), postembolization syndrome with liver toxicity (raised enzymes, frequent) and liver failure (defined as the inability of the liver to perform its normal synthetic and metabolic function as part of normal physiology, very rare)

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients with biopsy proven liver dominant (over 50% volume) metastasis of breast carcinoma

Exclusion criteria

1: significant extrahepatic disease representing an eminent life-threatening outcome
2: more than 75% of hepatic parenchymal involvement

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2012
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Product type:	Medicine

Brand name:	DC Bead®
Generic name:	DC Bead®
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	doxorubicin-HCl
Generic name:	doxorubicin-HCl
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	13-06-2012
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	09-10-2012
Application type:	First submission
Review commission:	METC NedMec

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	EUCTR2012-000973-22-NL
CCMO	NL39972.031.12