Phase II trial with melphalan for percutaneous chemosaturation (CS-PHP-Mephalan) in treating unresectable liver metastases of uveal melanoma

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Primary objective • To determine the overall response rate of two PHP with an at least 6 week interval and 3 mg/kg melphalan in irresectable liver metastases patients. • To determine the percentage of patients qualifying for resection. Secondary…

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

Summary

ID

NL-OMON44964

Source
ToetsingOnline

Brief title
CS-PHP-melfalan Uveal

Condition

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

Synonym
livermetastases, livermetastases of uveal melanoma

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: melphalan, percutaneous isolated hepatic perfusion, uveal melanoma

Outcome measures

Primary outcome

• Response rate expressed by RECIST criteria, after two percutaneous liver

perfusions with melphalan and an at least six week interval

• Number of curative resections after percutaneous perfusion

Secondary outcome

• Safety of percutaneous liver perfusions with the Delcath 2nd generation

system

• Overall survival and overall progression free survival

• Duration of response and duration of stable disease

• Quality of life

Study description

Background summary

Isolated therapy of the liver has the advantage of treating livermetastases, while symptoms and side effects are limited.
The aim of this phase II trial is to show the effectivity and safety of percutaneous isolated hepatic perfusion in treating patients with unresectable livermetastases. Uveal melanoma disseminates hematogenously, with a high propensity for liver, which is typical and most common site of metastasizing, followed by lung and bones. In a majority of patients with hepatic lesions, this is the only site of metastases.

Study objective

Primary objective
• To determine the overall response rate of two PHP with an at least 6 week interval and 3 mg/kg melphalan in irresectable liver metastases patients.
• To determine the percentage of patients qualifying for resection.

Secondary Objective
• To assess safety of PHP using the Generation 2nd Delcath system in patients with irresectable liver metastases.
• To determine the overall survival and overall progression free survival
• To determine the duration of response and duration of stable disease
• To determine the quality of life after two percutaneous liver perfusions.

Study design

A phase II two center trial performing a percutaneous hepatic perfusion in patients with irresectable liver metastases of uveal melanoma.

Intervention

When all inclusion and exclusion criteria are met, a percutaneous hepatic perfusion will be performed twice, with an at least 6 week interval between the first and the second procedure. The perfusion procedure is extensively described in the protocol.

Study burden and risks

Instead of systemic chemotherapeutics, the patients receives isolated hepatic perfusion twice, and one angiography. This treamtent constists of less day admited in hospital, and no systemic effect of chemotherapeutics.

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

• Informed consent
• Liver metastases of histologically confirmed primary uveal melanoma
• When resection of primary tumor, this has to be > 1 month before PHP and having fully recovered from surgery
• Unresectable metastases metastases confined to the liver based on CT-Thorax/abdomen and PET imaging
• Metastases measurable on CT-scan
• Life expectancy > 4 months
• APTT < 32.5 sec (<= 1.5 times ULN if considered due to tumor)
• PT < 13.7 sec (<= 1.5 times ULN if considered due to tumor)

Exclusion criteria

• Biological age <18 and >75 years
• WHO performance status >= 2 (Appendix A)
• < 40% healthy liver tissue
• Aberrant vascular anatomy or vascular abnormalities (e.g. severe atherosclerosis, vascular dissections), which impede PHP
• Severe comorbidity (e.g. cardiovascular and pulmonary disease precluding general anaesthesia, diabetes with nephropathy, active infections, other liver disease)
• Incompetent / Mentally disabled
• Pregnancy, inadequate contraception
• Intracranial lesions with a propensity to bleed (on Brain CT or MRI)

• LDH (> 2 times ULN)

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-02-2014
Enrollment:	34
Type:	Actual

Medical products/devices used

Generic name:	Delcath generation 2 system
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	26-11-2013
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO Date:	03-06-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
Approved WMO	

Date:	20-04-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 21170
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL45988.058.13
OMON	NL-OMON21170