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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21170

Source
Nationaal Trial Register

Health condition

livermetastases of uveal melanoma

Sponsors and support

Primary sponsor: LUMC, Leiden University Medical Centre
Source(s) of monetary or material Support: Delcath

Intervention

Outcome measures

Primary outcome

- Objective response rate expressed as the RECIST 1.1 criteria (Appendix A)

- Percentage of patients whose metastases turned into resectable ones

Secondary outcome

- Safety of percutaneous liver perfusion with the Delcath 2nd generation system

- Overall survival, overall progression free survival and hepatic progression free survival

- Duration of the response and duration of stable disease in patients with uveal melanoma metastases

- Quality of life (QoL), according to the EORTC QLQ-C30

Study description

Background summary

In this phase II trial patients with unresectable isolated hepatic metastases of uveal melanoma will be included to receive percutaneous hepatic perfusion (PHP) using Melphalan, this perfusion will be performed twice or more.

Study objective

Isolated liver perfusion has the advantage of controlling liver disease and decreasing treatment related symptoms and complications. This phase
II trial aims to study the effectiveness and safety of the PHP treatment with Melphalan in patients with unresectable liver metastases.

Study design

6 weeks after the perfusion, a CT-scan will be made, evaluating the effect of the procedure using the RECIST criteria. Safety and feasibility is monitored during the procedure. Overall survival, progression free survival is evaluated after the last patients has been treated.

Intervention

Percutaneous hepatic perfusion is performed with 3 mg/kg melphalan in uveal melanoma liver metastases patients. This procedure uses an intravascular perfusion system to infuse the melphalan, to filter the chemosaturated blood and return the filtered blood to the patient. Six weeks after the PHP procedure, the response rate will be determined by a CT-scan, using the RECIST criteria.

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Eligibility criteria

Inclusion criteria

- Liver metastases only of histologically confirmed uveal melanoma

- In case of resection of primary tumor, this should be > 1 month before PHP and has fully recovered from surgery.

- Unresectable metastases confined to the liver based on CT-Thorax/abdomen and PET imaging

- Metastases measurable on CT-scan meeting criteria for target lesion(s) by RECIST 1.1

- Candidate for neoadjuvant therapy as discussed in the multidisciplinary meeting to downsize the tumor

- No or prior systemic chemotherapy for colorectal adenocarcinoma

- Informed consent

- Life expectancy > 4 months

- Leukocytes ≥ 3.0 X 10^9/L

- Thrombocytes ≥ 100 X 10^9/L

- Creatinine clearance ≥ 60 ml/min

- APTT < 32.5 sec

- PT < 13.7 sec

- Aspartate aminotransferase (AST [SGOT]) and alanine aminotransferase (ALT [SGPT]) ≤ 2.5 times ULN, (≤ 5 times ULN if considered due to tumor)

- Serum bilirubin ≤ 1.5 times ULN

- Alkaline phosphatase ≤ 2.5 times ULN, (≤ 5 times ULN in case of livermetastases)

Exclusion criteria

- Biological age <18 and >65 years

- WHO performance status ≥ 2 (Appendix A)

- < 40% healthy liver tissue on CT

- Aberrant vascular anatomy or lesions, which impede PHP (e.g. aberrant right or left hepatic artery, severe atherosclerosis, vascular dissections). Embolization may be used to re-distribute liver vasculature.

- Prior Whipple's surgery

- 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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-09-2013
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	08-08-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44964
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3947
NTR-old	NTR4112
CCMO	NL45988.058.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON44964

Study results

Summary results
N/A