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

Gepubliceerd: 08-08-2013 Laatst bijgewerkt: 19-03-2025

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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21170

Bron
Nationaal Trial Register

Aandoening

livermetastases of uveal melanoma

Ondersteuning

Primaire sponsor: LUMC, Leiden University Medical Centre
Overige ondersteuning: Delcath

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

- Percentage of patients whose metastases turned into resectable ones

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Box 9600
A.L. Vahrmeijer
Leiden 2300 RC
The Netherlands
+31 (0)71 526 2309

Wetenschappelijk

Box 9600
A.L. Vahrmeijer
Leiden 2300 RC
The Netherlands
+31 (0)71 526 2309

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	15-09-2013
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	08-08-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44964
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A