Adjuvant immunotherapy after surgery for patients with peritoneal mesothelioma

No registrations found.

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

Summary

ID

NL-OMON28091

Source
Nationaal Trial Register

Brief title
MESOPEC

Health condition

Peritoneal mesothelioma

Sponsors and support

Primary sponsor: Erasmus Medical Center, Rotterdam
Source(s) of monetary or material Support: KWF Kankerbestrijding (Dutch Cancer Society)

Intervention

Outcome measures

Primary outcome

The main goal of this project is to determine the feasibility of administering DCBI after CRS-HIPEC in patients with malignant peritoneal mesothelioma.

Secondary outcome

Secondary endpoint of this study is to assess safety in patients with peritoneal mesothelioma who are treated with DCBI, which has already been proven in patients with pleural mesothelioma. Another secondary endpoint of this study is the determination of an immunological response against the tumor as result of the adjuvant therapy.

Study description

Background summary

The MESOPEC study is a single center, fase II study, that will be performed by the Erasmus MC Cancer Institute. The main goal of this study is to determine the feasibility of adjuvant dendritic cell based immunotherapy after cytoreductive surgery and hyperthermic intraperitoneal chemotherapy for patients diagnosed with peritoneal mesothelioma.

Study objective

Malignant peritoneal mesothelioma (MPM) is an uncommon but aggressive neoplasm. MPM has low survival rates of approximately one year even after palliative surgery and/or systemic chemotherapy. Recent advances in treatment strategies focusing on cytoreductive surgery (CRS) and hyperthermic intraperitoneal chemotherapy (HIPEC) have resulted in improved median survival.
However, recurrence rates are high. Current systemic chemotherapy in the adjuvant setting is of limited efficacy, while immunotherapy with dendritic cell based immunotherapy (DCBI) has yielded promising results in murine models with peritoneal mesothelioma and in patients with pleural mesothelioma.
Objective of this study is to assess the feasibility of administering DCBI after CRS-HIPEC in patients with MPM.

Study design

The end of the study is defined as the last patient’s last visit.

Intervention

Adjuvant dendritic cell based immunotherapy; before undergoing CRS-HIPEC a leukapheresis is performed of which the monocytes are used for differentiation to dendritic cells (DCs) using specific cytokines. Pulsed autologous DCs are re-injected after recovery from surgery (8-10 weeks), 3 times every two weeks. After the third injection with DCs revaccinations to boost the immune system are given after 3 and 6 months.

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria, before undergoing CRS-HIPEC:

• Patients with a histologically or cytologically confirmed diagnosis of malignant peritoneal mesothelioma

• Patients must be at least 18 years old and must be able to give written informed consent

• Patients must be ambulatory (WHO-ECOG performance status 0 or 1) and in stable medical condition

• Patients must have normal organ function and adequate bone marrow reserve: absolute neutrophil count >1.0 *109/l, platelet count >100*109/l and Hb >6.0mmol/l

• Ability to return to the study center for adequate follow-up and vaccinations

• Positive DTH skin test (induration > 2mm after 48 hrs) against at least one positive control antigen tetanus toxoid.

• Written informed consent according to the ICH-GCP

• Planned start date of vaccination within 8-10 weeks after CRS-HIPEC

• The expected survival must be at least 6 months

• Ability to return to the Erasmus MC for adequate follow-up as required by this protocol

Exclusion criteria

A potential participant who meets any of the following criteria will be excluded from participation in the study:

• Extra-abdominal disease/ metastatic disease

• Medical or psychological impediment to probable compliance with the protocol

• Current use of steroids or other immunosuppressive agents. Patients must have had six weeks of discontinuation before the first vaccination and must stop any such treatment during the time of the study on the basis of potential immune suppression. Prophylactic usage of dexamethasone during chemotherapy is excluded from that 6 weeks interval.

• No valid indication for CRS and HIPEC as determined by the surgical team

• Subject with any previous malignancy except: adequately treated basal cell or squamous cell skin cancer, superficial or in-situ cancer of the bladder or other cancer for which the subject has been disease-free for at least 3 years or any malignancy that requires no active treatment

• Serious concomitant disease or active infections

• History of auto-immune disease or organ allografts, or with active or chronic infection, including HIV and viral hepatitis

• Serious intercurrent chronic or acute illness such as pulmonary (COPD or asthma) or cardiac (NYHA class III or IV) or hepatic disease or other illness considered by the study coordinator to constitute an unwarranted high risk for CRS-HIPEC or investigational DC treatment

• Pregnant or lactating women

• Inadequate peripheral vein access to perform leukapheresis

• Concomitant participation in another clinical trial

• An organic brain syndrome or other significant psychiatric abnormality which would comprise the ability to give informed consent, and preclude participation in the full protocol and follow-up

• Absence of assurance of compliance with the protocol

• Patients with a known allergy to shell fish (may contain KLH)

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2018
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	27-02-2018
Application type:	First submission

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
NTR-new	NL6882
NTR-old	NTR7060
Other	NL60856.000.17 : MEC

Study results

Summary results

de Boer NL, van Kooten JP, Burger JWA, Verhoef C, Aerts J, Madsen EVE. Adjuvant dendritic cell based immunotherapy (DCBI) after cytoreductive surgery (CRS) and hyperthermic intraperitoneal chemotherapy (HIPEC) for peritoneal mesothelioma, a phase II single centre open-label clinical trial: rationale and design of the MESOPEC trial. BMJ Open. 2019;9(5):e026779.

van Kooten JP, de Boer NL, Burger JWA, Verhoef C, Aerts J, Madsen EVE. Adjuvante Dendritische Cel Immunotherapie na Cytoreductieve Chirurgie en Hypertherme Intraperitoneale Chemotherapie voor patiënten met Maligne Peritoneaal Mesothelioom. De MESOPEC studie. Nederlands Tijdschrift voor Oncologie. Jaargang 16, Nummer 2, Maart 2019.