Dendritic cell immunotherapy for patients with resected pancreatic cancer

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We hypothesized that mesothelioma lysate–pulsed dendritic cell immunotherapy induces an immune response that is beneficial for pancreatic cancer.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Exocrine pancreas conditions
Study type	Interventional

Summary

ID

NL-OMON28791

Source
NTR

Brief title
REACtiVe Trial

Condition

- Exocrine pancreas conditions

Health condition

Pancreatic cancer, alvleesklierkanker, pancreascarcinoom

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus Medical Center
Source(s) of monetary or material Support: TKI

Intervention

Explanation

Outcome measures

Primary outcome

The main goal of this study is to determine feasibility of MesoPher maintenance therapy in pancreatic cancer patients who underwent a radical tumor resection and received standard of care.

Secondary outcome

Secondary objectives are safety assessment after dendritic cell vaccination and the determination of an immunological response in blood with emphasis on T lymphocytes.

Study description

Background summary

The REACtiVe Trial is a single center, phase II study, that will be performed by the Erasmus Medical Center in Rotterdam. The main goal of this study is to determine the feasibility of dendritic cell based immunotherapy after surgery and standard of care for patients diagnosed with pancreatic cancer.

Study objective

We hypothesized that mesothelioma lysate–pulsed dendritic cell immunotherapy induces an immune response that is beneficial for pancreatic cancer.

Study design

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

Intervention

Leukapheresis is performed after which monocytes are used for differentiation to dendritic cells. Pulsed autologous dendritic cells (MesoPher) are re-injected 3 times every 2 weeks. After the 3rd injection with MesoPher, revaccinations to boost the immune system are given after 3 and 6 months.

Contacts

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Eligibility criteria

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

Inclusion criteria

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

- Surgically resected pancreatic cancer.

- Completed post-operative standard treatment. Standard of care treatment includes the choice of adjuvant chemotherapy. Patients who did not complete adjuvant chemotherapy due to toxicity or who are not able to start standard of care due to specific reasons are allowed to participate in the study after approval of the coordinating investigator.

- No disease activity as assessed by radiological imaging.

- 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 0,1 or 2) and in stable medical condition.

- Patients must have normal organ function and adequate bone marrow reserve: absolute neutrophil count > 1.0 x 109/l, platelet count > 100 x 109/l, and Hb > 6.0 mmol/l (as determined during screening).

- Positive DTH skin test (induration > 2mm after 48 hrs) against at least one positive control antigen tetanus toxoid (see section 8.3 for DTH skin test procedure).

- Women of childbearing potential must have a negative serum pregnancy test at screening and a negative urine pregnancy test just prior to the first study drug administration on Day 1, and must be willing to use an effective contraceptive method (intrauterine devices, hormonal contraceptives, contraceptive pill, implants, transdermal patches, hormonal vaginal devices, infusions with prolonged release) or true abstinence (when this is in line with the preferred and usual lifestyle)* during the study and for at least 12 months after the last study drug administration. *True abstinence is acceptable when this is in line with the preferred and usual lifestyle of the subject. Periodic abstinence (such as calendar, ovulation, symptothermal, postovulation methods) and withdrawal are not acceptable methods of contraception.

- Men must be willing to use an effective contraceptive method (e.g. condom, vasectomy) during the study and for at least 12 months after the last study drug administration.

- Ability to return to the hospital for adequate follow-up as required by this protocol.

- Written informed consent according to ICH-GCP.

Exclusion criteria

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

- Medical or psychological impediment to probable compliance with the protocol.

- Current or previous treatment with immunotherapeutic agents.

- Current use of steroids (or other immunosuppressive agents). Patients must have had 6 weeks of discontinuation and must stop any such treatment during the time of the study. Prophylactic usage of dexamethasone during chemotherapy is excluded from this 6 weeks interval.

- Prior 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 patient has been disease-free for five years.

- Serious concomitant disease, or active infections.

- History of autoimmune disease or organ allografts (or with active acute or chronic infection, including HIV and viral hepatitis).

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

- Known allergy to shell fish (may contain keyhole limpet hemocyanin (KLH)).

- Pregnant or lactating women.

- Inadequate peripheral vein access to perform leukapheresis.

- Concomitant participation in another clinical intervention trial (except participation in a biobank study).

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

- Absence of assurance of compliance with the protocol. Lack of availability for follow-up assessment.

Study design

Design

Study phase:	1-2
Study type:	Interventional
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-02-2019
Enrollment:	10
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Approved WMO Date:	06-11-2018
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Study registrations

Followed up by the following (possibly more current) registration

ID: 52670
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7432
NTR-old	NTR7674
CCMO	NL67169.000.18
OMON	NL-OMON52670

Study results