Natural Killer cel therapie tegen teruggekeerde eierstokkanker.

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Natural killer cells are cells of the innate immunesystem and can kill tumor cells without prior sensitization. By infusing these cells through a catheter in the intraperitoneal cavity, ovarian carcinoma cells can be traced and killed. This phase 1...

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

Summary

ID

NL-OMON20648

Source
NTR

Brief title
INTRO-studie

Health condition

Recurrent ovarian carcinoma, recidief ovarium carcinoom. immunotherapy, immuuntherapie.

Sponsors and support

Primary sponsor: Radboudumc
Source(s) of monetary or material Support: KWF

Intervention

Outcome measures

Primary outcome

Safety and toxicity of intraperitoneal NK cells.

Secondary outcome

In vivo detection and expansion of the transfused UCB-NK cells, detection of biological NK cell activity and effect on CA-125 levels

Study description

Background summary

This study is a phase I safety and feasibility study in a series of 12 patients who are suffering from recurrent ovarian, fallopian tube or primary peritoneal cancer. Prior to NK cell infusion, a laparoscopy is performed to place a catheter in the peritoneal cavity. The first cohort of three patients will receive an intraperitoneal infusion of between 1.5x 109 and 3x109 allogeneic UCB-NK cells generated ex vivo from CD34+ hematopoietic progenitor cells obtained from an allogeneic UCB unit without a preparative regimen. In the second group of three patients the same UCB-NK cell dosage will be given with a preparative regimen of four days non-myeloablative immunosuppressive conditioning regimen with cyclophosphamide and fludarabine (CyFlu). If no severe toxicity is seen in these 6 patients, an extension cohort of 6 patients will be included to answer the secondary objective. The primary aim of our study is to evaluate safety and toxicity of intraperitoneal infusion of ex vivo-expanded NK cells from CD34+ umbilical cord blood (UCB) progenitor cells with and without a preceding non-myeloablative immunosuppressive conditioning regimen in patients suffering from recurrent ovarian, fallopian tube or primary peritoneal cancer. Secondary objectives are to compare the in vivo lifespan, expansion and biological activity of intraperitoneal infused NK cell products with and without preparative chemotherapy, and effects on disease.

Study objective

Natural killer cells are cells of the innate immunesystem and can kill tumor cells without prior sensitization. By infusing these cells through a catheter in the intraperitoneal cavity, ovarian carcinoma cells can be traced and killed. This phase 1 study is designed to look at the safety and toxicity.

Study design

Trial will start including on 1st of march 2018.

Intervention

Intraperitoneal natural killer cell therapy with and without preconditioning chemotherapy regimen.

Contacts

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Eligibility criteria

Inclusion criteria

• Patients suffering from their second recurrence of ovarian, fallopian tube or primary peritoneal cancer, with an elevated serum level of CA-125 on two successive time points with 28 days in between, reaching a value of more than 2 times nadir and above 35 U/ml without gastrointestinal symptoms.
• Able to undergo laparoscopic IP port placement and IP treatment administration
• Adequate organ function
• Age 18 years or older
• Age under 76 years.
• Karnofsky performance status >70% (see appendix 2)
• Life expectancy > 6 months
• At least 28 days after last anti cancer treatment, before start of preparative regimen
• Written informed consent

Exclusion criteria

• Patients on immunosuppressive drugs
• Patients with active infections (viral, bacterial or fungal) that requires specific therapy. Acute anti-infectious therapy must have been completed within 14 days prior to study treatment
• Laparoscopic adhesion score >4 out of 9.

• Severe cardiovascular disease (arrhythmias requiring chronic treatment, congestive heart failure or symptomatic ischemic heart disease (appendix 4)
• Severe pulmonary dysfunction (CTCAE III-IV) (appendix 4)
• Severe renal dysfunction (MDRD<50) (appendix 4)
• Severe hepatic dysfunction (serum bilirubin or transaminases > 3 times normal level) (appendix 4)
• Severe neurological or psychiatric disease

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2018
Enrollment:	12
Type:	Anticipated

Ethics review

Positive opinion

Date:	08-11-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45699
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6785
NTR-old	NTR6970
EudraCT	2016-00-299-78
CCMO	NL60937.000.17
OMON	NL-OMON45699

Study results