Intraperitoneal infusion of ex vivo cultured allogeneic Natural Killer cells in recurrent ovarian carcinoma patients.

Published: 07-06-2017
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The objective is to evaluate safety, toxicity and expansion of intraperitoneally infused UCB-derivedex vivo-generated NK cells in patients diagnosed with recurrent ovarian cancer. Infusion with and without lymphodepleting chemotherapy will be...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive neoplasms female malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON45699

Source
ToetsingOnline

Brief title
INTRO

Condition

- Reproductive neoplasms female malignant and unspecified

Synonym
Ovarian carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: KWF

Intervention

Keyword: Immune therapie, Natural Killer cell, Ovarian carcinoma, Recurrence

Outcome measures

Primary outcome

Safety and toxicity of intraperitoneal UCB-NK cell infusion in combination with

IL-2 support, with versus without a preceding lymphodepleting conditioning

regimen

Secondary outcome

Secondary objectives are in vivo lifespan, proliferation and functional

activity of infused NK cells and preliminary effect on peritoneal disease using

CA-125 serum levels.

Study description

Background summary

Recurrent ovarian carcinoma is incurable, but prolonged survival upon therapy is possible in some patients. The 5-year survival is 46% for all stages of ovarian cancer, and 28% for advanced stage disease. Notably, almost 70% of women with ovarian cancer present with stage III or IV disease for which the rate of recurrence is 70-90%. As most women with relapsed or metastatic cancer will die of progressive disease, there is a medical need for novel therapeutic strategies.

Study objective

The objective is to evaluate safety, toxicity and expansion of intraperitoneally infused UCB-derived
ex vivo-generated NK cells in patients diagnosed with recurrent ovarian cancer. Infusion with and without lymphodepleting chemotherapy will be compared for UCB-NK cell persistence and expansion that is crucial for clinical benefit.

Study design

Phase 1 safety study in 4 cohorts of 3 patients. The first 3 patients will receive NK cell infusion alone, the second cohort will get NK cell infusion with a preparative chemotherapy regimen. In the extension cohort of 6 patients we will look at NK cell expansion with and without preparative chemotherapy, to be able to decide whether preparitive chemotherapy is neccesary.

Intervention

Intraperitoneal UCB-NK cell infusion of UCB-NK cells in combination with IL-2 support, with versus without a preceding lymphodepleting conditioning regimen.

Study burden and risks

All patients start with intraperitoneal placement of the IP catheter per laparoscopy in daycare. The first group will be admitted in the hospital for 14 days for chemotherapy and will receive the intraperitoneal NK cell infusion in the same setting. The second group will have the intraperitoneal NK cell infusion in daycare. All patients will be seen for medical checkup, blood collection and peritoneal fluid collection on day 7, 14, 21 and 28, and for the first two on day 56.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patient with a second recurrence of ovarian cancer, based on increasing CA-125 levels, without symptoms. Patients are included after palliative chemotherapy for their first recurrence. Patients must have a life expectancy of >6 months and are only enrolled after prior given written informed consent. Patients should be able to undergo a laparoscopy.

Exclusion criteria

Patients with active infections or serious organ failure are excluded. Patients on immunesuppressive drugs and with recent chemotherapy (<28days ago).

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-06-2019
Enrollment:	12
Type:	Actual

Medical products/devices used

Product type:	Medicine

Generic name:	Somatic cels allogenic

Ethics review

Approved WMO Date:	07-06-2017
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	21-08-2018
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	08-10-2018
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	24-09-2019
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	17-12-2019
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	23-04-2020
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	30-07-2020
Application type:	Amendment

Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	07-12-2020
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	24-09-2021
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	04-11-2022
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	16-11-2022
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20648
Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2016-000299-78-NL
CCMO	NL60937.000.17
OMON	NL-OMON20648

Study results

Date completed: 28-08-2023

Actual enrolment: 10

Summary results

Trial is onging in other countries