Phase 3 study with OTL38 in ovarian cancer

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Ovarian cancer is the twelfth leading cause of cancer death in the United States. Based on data from SEER 18 2006-2012, the overall five-year survival rate is 46.2% and for distant and unstaged disease it is only 24-28% (SEER 2016; Kosary 2007). The...

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

Samenvatting

ID

NL-OMON27574

Bron
NTR

Verkorte titel
CHDR1848

Aandoening

Ovarian cancer

Ondersteuning

Primaire sponsor: On Target Laboratories, LLC
Overige ondersteuning: Sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

• Proportion of patients with at least one evaluable FR+ ovarian cancer lesion confirmed by central pathology (Standard of truth) that was detected using the combination of OTL38 and

fluorescent light but not under normal light or palpation. All evaluable FR+ ovarian cancer lesions that were identified prior to or after surgery, that were detected using the combination of OTL38 and fluorescent light but not under normal light or palpation, and were removed based on the evaluation under fluorescent light, will be included in the calculation of the proportion of patients with at least one FR+ ovarian cancer lesion confirmed by central pathology. The primary endpoint will be determined based on evaluable lesions as described below.
• Evaluable lesions are defined as follows: lesions that do not appear on an organ or tissue that was intended for removal based on the Pre-Fluorescence Surgical Plan, regardless of the absence or presence of tumor.

Toelichting onderzoek

Achtergrond van het onderzoek

Ovarian cancer is the twelfth leading cause of cancer death in the United States. Based on data from SEER 18 2006-2012, the overall five-year survival rate is 46.2% and for distant and unstaged disease it is only 24-28% (SEER 2016; Kosary 2007). The standard management of primary ovarian cancer is optimal cytoreductive surgery (usually defined as reduction of residual disease to less than 1 to 2 cm) followed by chemotherapy (Al Rawahi 2013). Experts are advocating complete cytoreductive surgery for tumor debulking as it results in better overall
survival than optimal cytoreduction (Shih 2010). Although tumor debulking surgery is the cornerstone of current treatment in patients, the lesions can be diffuse and numerous, of various sizes, and often not readily visible in the surgical field, leading to varying rates of optimal cytoreduction among surgeons (Ibeanu 2010). This is an
important factor in the poor prognosis for patients with advanced ovarian cancer. Tumor-specific intraoperative fluorescence imaging may improve staging and debulking efforts in cytoreductive surgery.

Doel van het onderzoek

Ovarian cancer is the twelfth leading cause of cancer death in the United States. Based on data from SEER 18 2006-2012, the overall five-year survival rate is 46.2% and for distant and unstaged disease it is only 24-28% (SEER 2016; Kosary 2007). The standard management of primary ovarian cancer is optimal cytoreductive surgery (usually defined as reduction of residual disease to less than 1 to 2 cm) followed by chemotherapy (Al Rawahi 2013). Experts are advocating complete cytoreductive surgery for tumor debulking as it results in better overall
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fluorescence imaging may improve staging and debulking efforts in cytoreductive surgery.

Onderzoeksopzet

Day 1, Day 7 (± 4) and Day 28 (± 4)

Onderzoeksproduct en/of interventie

Administration of OTL38 and use of a fluorescent imaging system during surgery

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Female patients 18 years of age and older
2. Have a primary diagnosis, or at high clinical suspicion, of primary ovarian cancer (of epithelial type), planned for primary surgical cytoreduction, interval debulking, or have recurrent ovarian cancer surgery, and:
o Who are scheduled to undergo laparotomy for the debulking surgery OR
o Who are scheduled to undergo laparoscopy and pre-authorized to undergo laparotomy for the debulking surgery if cancer is detected on the laparoscopy
3. A negative serum pregnancy test at Screening followed by a negative urine pregnancy test on the day of surgery or day of admission for female patients of childbearing potential.

4. Female patients of childbearing potential or less than 2 years postmenopausal agree to use an acceptable form
of contraception from the time of signing informed consent until 30 days after study completion
5. Ability to understand the requirements of the study, provide written informed consent for participation in the
study and authorization of use and disclosure of protected health information, and agree to abide by the study restrictions and to return for the required assessments.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Previous exposure to OTL38
2. Known FR-negative ovarian cancer
3. Planned surgical debulking via laparoscopy or robotic surgery, with no intent of laparotomy.
4. Patients with known ovarian cancer miliary disease prior to surgery
5. Any medical condition that, in the opinion of the investigators, could potentially jeopardize the safety of the
patient
6. History of anaphylactic reactions
7. History of allergy to any of the components of OTL38, including folic acid
8. Pregnancy or positive pregnancy test
9. Clinically significant abnormalities on electrocardiogram (ECG)
10.Presence of any psychological, familial, sociological or geographical condition potentially hampering
compliance with the study protocol and follow-up schedule
11.Impaired renal function defined as eGFR< 50 mL/min/1.73m2
12.Impaired liver function defined as values > 3x the upper limit of normal (ULN) for alanine aminotransferase
(ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP), or total bilirubin.
13.Known Stage IV ovarian cancer with brain metastases
14.Received an investigational agent in another clinical trial within 30 days prior to surgery
15.Known sensitivity to fluorescent light

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel

Toewijzing:	N.v.t. / één studie arm
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2019
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	15-04-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48066
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7675
CCMO	NL68086.056.18

Register	ID
OMON	NL-OMON48066

Resultaten