Body surface area-based vs concentration-based dosing of cisplatin for hyperthermic intraperitoneal chemotherapy (HIPEC) in women with advanced ovarian cancer

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This study has been transitioned to CTIS with ID 2024-514711-99-00 check the CTIS register for the current data. To evaluate BSA-based versus concentration-based OVHIPEC with cisplatin in patients with advanced-stage ovarian cancer.

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

Summary

ID

NL-OMON56202

Source
ToetsingOnline

Brief title
CisCon

Condition

- Reproductive neoplasms female malignant and unspecified

Synonym
ovarian cancer

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: onderzoeksreserves en giften

Intervention

Keyword: dosing, HIPEC, interval cytoreductive surgery, ovarian cancer

Outcome measures

Primary outcome

Primary endpoint is platinum concentration in the tumor nodule at the end of the HIPEC procedure.

Secondary outcome

Secondary endpoints are pharmacokinetic parameters (AUCip, Cmax, Tmax, t1/2 in perfusate, clearance from abdominal cavity), platinum concentration in normal tissue, platinum concentration in tumor tissue after 30 min and 60 min of perfusion, and post-operative complications (CTCAE 5.0), Recurrence-free survival (RFS) and Overall survival (OS)

Study description

Background summary

Cytoreductive surgery (CRS) with the addition of hyperthermic intraperitoneal chemotherapy (HIPEC) is used in current clinical practice in selected patients with advanced ovarian cancer. Clinical evidence for the benefit of HIPEC in ovarian cancer comes from the pivotal phase 3 OVHIPEC trial [1]. Worldwide, two established strategies exist for dosing of HIPEC protocols, which follow either a body surface area (BSA)-based or a concentration-based approach [1-4]. Since both strategies result in different exposure to intra-peritoneal chemotherapy, we aim to compare the pharmacokinetics and safety of both strategies.

Study objective

This study has been transitioned to CTIS with ID 2024-514711-99-00 check the CTIS register for the current data.

To evaluate BSA-based versus concentration-based OVHIPEC with cisplatin in patients with advanced-stage ovarian cancer.

Study design

Single-center phase II randomized study

Intervention

Patients in Arm A are treated with interval cytoreductive surgery (with no more than 1 cm residual disease) and cispaltin-based HIPEC with a dosage of 100 mg/m2, with a maximum dose of 220 mg
Patients in Arm B are treated with interval cytoreductive surgery (with no more than 1 cm residual disease) and cisplatin- based HIPEC with a dosage of 40 mg/L perfusate.

Study burden and risks

Previous studies have shown that both dosing regimens are safe. We do not expect to observe a significant difference in adverse events. Peritoneal biopsies for research during and at the end of the HIPEC procedure do not lead to additional risks after performing extensive cytoreductive surgery. Participation does not require extra hospital visits or examinations and regular follow-up will be in place for both arms.

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

1. signed and written informed consent
2. age >= 18 years
3. patients eligible for interval cytoreductive surgery with OVHIPEC
a. histological proven FIGO stage III primary high grade serous ovarian, fallopian tube, or extra-ovarian cancer
b. when only cytology is performed to confirm the diagnosis ovarian carcinoma, immunohistochemistry including keratin 7, keratin 20, p53, PAX8 should be considered (at the discretion of the pathologist)
c. neo-adjuvant chemotherapy consists of (at least) 3 courses of carboplatin/paclitaxel
d. following 2 cycles of chemotherapy no progression should occur
e. resectable, local bowel involvement, iatrogenic abdominal wall metastases or umbilical lesions (which is stage IV) are allowed;
4. peritoneal disease present at the start of cytoreductive surgery
5. treated with optimal or complete interval cytoreductive surgery
6. fit for major surgery, WHO performance status 0-2
7. adequate bone marrow function (hemoglobin level >5.5 mmol/L; leukocytes >3 x 109/L; platelets >100 x 109 /L)
8. adequate hepatic function (ALT, AST and bilirubin <2.5 times upper limit of normal)
9. adequate renal function (creatinine clearance >= 60 ml/min using Cockcroft-Gault formula or 24-hour measurement or ml/min/1,73 m2 using MDRD or CKD-EPI)
10. able to understand the patient information

Exclusion criteria

1. history of previous malignancy treated with chemotherapy
2. opting for fertility-sparing surgery

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2022
Enrollment:	40
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Cisplatin
Generic name:	Cisplatin
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	02-05-2022
Application type:	First submission
Review commission:	METC NedMec

Approved WMO Date:	23-05-2022
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	27-07-2023
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	01-09-2023
Application type:	Amendment
Review commission:	METC NedMec

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
EU-CTR	CTIS2024-514711-99-00
EudraCT	EUCTR2021-006809-29-NL
ClinicalTrials.gov	NCT05406674
CCMO	NL80234.031.22