Will the use of the PlasmaJet device improve the rate of complete cytoreductive surgery for advanced stage ovarian cancer: a randomized controlled trial in The Netherlands (PlaComOv-study).

No registrations found.

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

Summary

ID

NL-OMON21120

Source
NTR

Brief title
PlaComOv

Health condition

Advanced ovarian cancer

Cytoreductive surgery

Complete cytoreduction

PlasmaJet

Hoogstadium eierstokkanker

Complete debulking

chirurgie

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

Rate of complete cytoreductive surgery in the PlasmaJet versus control group with electrosurgery.

Secondary outcome

1. Complications (30-day morbidity)

2. Quality of life

3. Duration of surgery

4. Blood loss

5. Length of hospital stay

6. Disease-free survival

7. Overall survival

8. Percentage of patients who have received a colostomy to achieve complete cytoreductive surgery

9. Cost per complete cytoreductive surgery and per life year gained

Study description

Background summary

Rationale:

The most important goal for surgery of advanced stage ovarian cancer is removal of all visible tumour in the abdomen, since removal of all tumor is associated with a prolonged survival. This is called complete cytoreductive surgery (CCS). With conventional surgical methods (electrosurgery) often, it is not possible to remove all visible tumour in case of many small metastases on the peritoneum and intestinal surface. In this research proposal we want to investigate whether the use of PlasmaJet Surgical Device increases the rate of a successful CCS, resulting in a longer progression free and overall survival.

Hypothesis:

Using PlasmaJet Surgical Device during surgery improves the rate of complete cytoreductive surgery in women with advanced ovarian cancer.

Objective:

Primary research question:

Does the use of PlasmaJet technique result in an increased number of complete cytoreductive surgery compared with conventional surgery using traditional electrosurgery in case of advanced stage ovarian cancer?

Secondary research questions:

1. Are there differences in the complication rate (30-day morbidity) between the PlasmaJet versus conventional surgery group?

2. Are there differences in quality of life after surgery with PlasmaJet versus conventional surgery?

3. Are there surgical technical differences (duration of surgery), blood loss, hospital stay, percentage of patients who require a colostomy to achieve complete cytoreductive surgery) between PlasmaJet versus conventional surgery group?

4. Are there any long-term differences in disease-free survival and overall survival between the PlasmaJet versus conventional surgery group?

Study design:

Multicenter single-blinded superiority RCT in 2 university and 9 non-university hospitals.

Study population:

Women diagnosed with advanced stage ovarian carcinoma (FIGO Stage IIIB-IV).

Intervention:

Use of the PlasmaJet device during cytoreductive surgery (intervention group) versus the use of standard surgical instruments combined with electrocoagulation (control group).

Main study parameters/endpoints:

Primary outcome:

Rate of complete cytoreductive surgery in the PlasmaJet versus control group with electrosurgery.

Secondary outcomes

1. Complications (30-day morbidity)

2. Quality of life

3. Duration of surgery

4. Blood loss

5. Length of hospital stay

6. Disease-free survival

7. Overall survival

8. Percentage of patients who have received a colostomy to achieve complete cytoreductive surgery

9. Cost per complete cytoreductive surgery and per life year gained

We want to demonstrate that it is possible to increase the percentage complete cytoreduction by 15% to 77% (conventional surgery 62%) by using the PlasmaJet, thereby prolonging progression free survival.

Study objective

Using PlasmaJet Surgical Device during surgery improves the rate of complete cytoreductive surgery in women with advanced ovarian cancer.

Study design

Complete cytoreduction: during/after surgery

30 days post surgery: 30 day morbidity

5 years: 5 year survival

Intervention

Use of the PlasmaJet device during cytoreductive surgery (intervention group) versus the use of standard surgical instruments combined with electrocoagulation (control group).

Contacts

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Eligibility criteria

Inclusion criteria

-patients with epithelial ovarian, tuba or peritoneal carcinoma FIGO IIIB-IV who are fit enough to undergo radical cytoreductive surgery as discussed in the multidisciplinary tumor board. Patients can either be scheduled for primary cytoreduction or for interval cytoreduction after neoadjuvant chemotherapy.

-patients should understand the patient information form and sign informed consent.

-pre-operative CT scan meets criteria for resectability

Exclusion criteria

-patients who are not willing to participate or not able to give their informed consent (language barrier) and patients who are not willing to undergo extensive surgery.

-patients who are unfit to undergo extensive surgery (assessed by gynaecologist and anaesthesiologist and discussed in MDO).

-patients who are not fit enough to get the standard complete chemotherapy (six cycles carboplatin paclitaxel) (assessed by medical oncologist and discussed in multidisciplinary tumor board).

-patients with a non-epithelial, borderline ovarian tumour or an ovarian metastasis of another primary tumour.

-patients with recurrence of ovarian cancer

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2017
Enrollment:	330
Type:	Anticipated

Ethics review

Positive opinion

Date:	16-08-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48869
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6446
NTR-old	NTR6624
CCMO	NL62035.078.17
OMON	NL-OMON48869

Study results

Summary results
Submitted