Evaluation of effectiveness of the PlasmaJet Surgical device in the treatment of Advanced Stage Ovarian Cancer.
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).

Published: 20-11-2017
Last updated: 15-05-2024

Hypothesis:Using PlasmaJet Surgical Device during surgery improves the rate of complete cytoreductive surgery in women with advanced ovarian cancer.Primary research question:Does the use of PlasmaJet technique result in an increased number of...

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

Summary

ID

NL-OMON48869

Source
ToetsingOnline

Brief title
PlaComOv

Condition

- Reproductive neoplasms female malignant and unspecified
- Obstetric and gynaecological therapeutic procedures

Synonym
ovarian cancer, Ovarian carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: ZonMW,Medical Dynamics,Plasma Surgical

Intervention

Keyword: Advanced stage ovarian cancer, Cytoreductive surgery, Debulking, PlasmaJet

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

10. Comparison of the completeness of surgery between both study groups

according to an independent review of the operation field photo's.

Study description

Background summary

The most important goal for surgery of advanced stage ovarian cancer is removal of all visible tumour in the abdomen, since removal of all tumour 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.

Study objective

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

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. Is it of additional value to make operation field photo*s to have an independent judgment of completeness of surgery?
5. Are there any long-term differences in disease-free survival and overall survival between the PlasmaJet versus conventional surgery group?

Study design

Multicentre single-blinded superiority RCT in 3 university and 10 non-university hospitals.

Intervention

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

Study burden and risks

In literature, the risks of using the new PlasmaJet technique seem to be negligible, but its efficacy has never been analysed in ovarian cancer surgery. The burden of participating women is minimal: no additional follow-up visits are necessary compared to the current standard care. They only have to fill in 7 QoL forms in 4 years even as the women in the control group.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40
Rotterdam 3015 GD
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40
Rotterdam 3015 GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

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 MDO. 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 platinum based chemotherapy, e.g. carboplatin/paclitaxel)) (assessed by medical oncologist and discussed in MDO).
- 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

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-02-2018
Enrollment:	330
Type:	Actual

Medical products/devices used

Generic name:	PlasmaJet
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	20-11-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	03-01-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-09-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-03-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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: 21120
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL62035.078.17
OMON	NL-OMON21120