# Treatment of metastatic vulvar carcinoma in a neoadjuvant setting with Carboplatin and Paclitaxel chemotherapy

Published: 26-11-2019
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Main objective: response rate and tumour size reduction by chemotherapy

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

## Summary

### ID

NL-OMON49490

**Source**
ToetsingOnline

**Brief title**
CRAVAT

### Condition

- Reproductive neoplasms female malignant and unspecified

**Synonym**
vulva carcinoma

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Antoni van Leeuwenhoek Ziekenhuis
**Source(s) of monetary or material Support:** gynaecologie AVL

## Intervention

**Keyword:** chemotherapy, metastatic, neoadjuvant, vulvar carcinoma

## Outcome measures

### Primary outcome

response rate and tumour size reduction by neo adjuvant chemotherapy.

### Secondary outcome

Secondary objectives are chemotherapy related morbidity will be monitored as

well as be

disease free and overall survival and patterns of recurrence.

# Study description

### Background summary

Vulvar cancer is a rare malignancy. Surgery is the treatment of choice, but frequently causes invalidating and chronic postoperative morbidity, especially in patients with high stage disease. Theoretically, downstaging with neo adjuvant chemotherapy could shrink the tumour, making surgical treatment less extensive thereby diminishing the chance for morbidity.

### Study objective

Main objective: response rate and tumour size reduction by chemotherapy

### Study design

a prospective, multi-centre phase II trial to investigate the response rate of carboplatin and paclitaxel in patients with vulvar carcinoma.

### Intervention

): a maximum of 6 courses of Paclitaxel 175 mg/m2 and Carboplatin AUC 5 in a 3 weekly schedule

**Study burden and risks**

- 1 to 4 extra site visits, namely before every new chemotherapy cycle.
- during these visits blood (2 tubes) will be investigated to check if the next chemotherapy cycle can be given safely.
- 1 extra visit after the 3rd cycle of chemotherapy for a gynaecological physical examination with measurement of the primal lesion(s) and a photo will be taken with a ruler.
-after the 3th cycle of chemotherapy CT scan will be repeated for measuring respons according to RECIST criteria.
- an extra biopsy of the tumour can be taken before starting chemotherapy or at the start of the operation, to investigate the microenvironment in relation to response.
- risks associated with the treatment are those already known: for example low amount of blood cells with risk of delaying (or not continuing) chemotherapy or wound infection or breakdown in case of an operation

# 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

• Woman >= 18 years
• Signed and written informed consent.
• Histologically confirmed squamous cell vulvar carcinoma
• World Health Organization performance status of 0-2
• Adequate hematological function
• Adequate hepatic function
• Adequate renal function
• Negative pregnancy test for woman of childbearing potential
• Histologically or CT scan confirmed metastatic squamous cell vulvar carcinoma
• Measurable disease
• TNM stage any T any N M1

### Exclusion criteria

• Vulvar cancer other than squamous cell carcinoma at biopsy
• Patients with metastasis limited to the pelvic lymph nodes, who can be primarily operated with curative intent
• Other diagnosis of malignancy or evidence of other malignancy for 5 years before screening for this study

## Study design

### Design

| | |
|---|---|
| Study phase: | 2 |
| Study type: | Interventional |
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 26-05-2020 |
| Enrollment: | 12 |
| Type: | Actual |

### Medical products/devices used

| | |
|---|---|
| Product type: | Medicine |
| Brand name: | Carboplatin Hospira |
| Generic name: | Carboplatin |
| Registration: | Yes - NL intended use |
| Product type: | Medicine |
| Brand name: | Paclitaxel Hospira |
| Generic name: | Paclitaxel |
| Registration: | Yes - NL intended use |

## Ethics review

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|---|---|
| Approved WMO Date: | 26-11-2019 |
| Application type: | First submission |
| Review commission: | METC NedMec |
| Approved WMO Date: | 16-01-2020 |
| Application type: | First submission |
| Review commission: | METC NedMec |
| Approved WMO Date: | 26-06-2020 |
| Application type: | Amendment |
| Review commission: | METC NedMec |
| Approved WMO Date: | 20-07-2020 |
| 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 |
|---|---|
| EudraCT | EUCTR2019-000851-15-NL |
| ClinicalTrials.gov | NCTnummervolgt |
| CCMO | NL69152.031.19 |