Treatment of locally advanced 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 neoadjuvant chemotherapy.

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

Summary

ID

NL-OMON48481

Source
ToetsingOnline

Brief title
VULCANize

Condition

- Reproductive neoplasms female malignant and unspecified

Synonym
vulvar 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, locally advanced, neo-adjuvant, vulvar carcinoma

Outcome measures

Primary outcome

response rate and tumour size reduction by neoadjuvant chemotherapy. Morbidity

and complication assessment

Secondary outcome

Secondary objectives are the avoidance of exenterative or invalidating surgery.

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 neoadjuvant 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 neoadjuvant chemotherapy.

Study design

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

Public
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
Amsterdam 1066CX
NL
Scientific
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
Amsterdam 1066CX
NL

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
• measurable disease by physical examination
• TNM stage T2, any N, M0

Exclusion criteria

• Vulvar cancer other than squamous cell carcinoma at biopsy
• Previous radiotherapy of the vulva, groins or pelvis
• 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):	11-03-2020
Enrollment:	51
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

Approved WMO Date:	26-11-2019
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	14-01-2020
Application type:	First submission
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	EUCTR2019-003104-12-NL
ClinicalTrials.gov	NCTnummervolgt
CCMO	NL71004.031.19