Phase II study of definitive radiochemotherapy for locally advanced squamous cell cancer of the vulva: an efficacy study

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The primary objective is to gain experience with primary radiochemotherapy and to determine the locoregional response rate at 12 weeks after radiochemotherapy and after groin dissection for cN1,2 patients.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive neoplasms male malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON30199

Source
ToetsingOnline

Brief title
radiotherapy for vulvar cancer

Condition

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

Synonym
vulvar cancer, vulvar neoplasm

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: KWF Kankerbestrijding

Intervention

Keyword: phase II, radiochemotherapy, vulvar neoplasm

Outcome measures

Primary outcome

The primary objective is to gain experience with primary radiochemotherapy and to determine the locoregional response rate at 12 weeks after radiochemotherapy and after groin dissection for cN1,2 patients.

Secondary outcome

The secondary objective would be to determine short-term morbidity defined as desquamation of the skin, infection, long-term morbidity defined as edema, fibrosis, the incidence of fecal and or urinary continence, and or incidence of reconstructive surgery performed and treatment related mortality. Longterm morbidity and the rate of locoregional recurrences will be evaluated at 24 months after the end of radiochemotherapy.

Study description

Background summary

Cancer of the vulva is a relatively rare disease with an annual incidence of 2-3 per 100.000 women. In the Netherlands each year 150-200 new patients are diagnosed with vulvar cancer In 30% of the patients tumors are classified as T3/T4 tumors with either extension of the tumor to the vagina, the proximal urethra or anus (cT3) or extension to the upper urethra or bladder, upper anal canal or rectum or the tumor is fixed to the pubic bone (cT4). The primary tumor causes serious local problems such as pain while sitting, discharge,

bleeding from necrotic tumor and a faul odor. Positive lymph nodes are found in 50%-60% of patients with T3/T4 tumors. Frequently these nodes are ulcerating and or fixed to the femoral vessels in the groin. These patients presenting with locally advanced disease (cT3/T4) pose a specific problem regarding the treatment. Traditionally exenterative surgery with stoma formation was the only available treatment.
Recently patients with locally advanced vulvar cancer (carcinoma of the vulva with unresectable N2/N3 groin lymph nodes) were treated with a combination of 4760 cGy radiotherapy (daily fractions 2 x 170 cGy and given as split course with an interval of 1* to 2* weeks) combined with concurrent chemotherapy (cisplatin and 5-FU). This resulted in the prevention of either a uro- or colostomy in 49 of 50 patients, although postoperative wound complications were frequent.
Therefore studies using a higher radiation dose combined with chemotherapy resulting in a higher local control rate precluding salvage surgery are warranted.

Study objective

The primary objective is to gain experience with primary radiochemotherapy and to determine the locoregional response rate at 12 weeks after radiochemotherapy and after groin dissection for cN1,2 patients.

Study design

The trial is a non-randomized multi-centre phase II study

Intervention

Lymph node debulking of enlarged groin lymph nodes (if applicable) followed by chemoradiotherapy towards the vulva and groins.

Study burden and risks

There is a higher risk on radiation related morbidity like vulvair and groin desquamation and diarrhoe.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
1105AZ Amsterdam

NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
1105AZ Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• squamous cell cancer of the vulva with locally advanced disease not curable with surgery unless extensive reconstructive surgery or a colostomy or urostomy is performed
• Amenable to curative treatment
• No disease present outside the pelvis
• Performance status WHO 0-2
• Patients must be fit enough to undergo salvage surgery after chemo radiotherapy

Exclusion criteria

none

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2006
Enrollment:	68
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Xeloda
Generic name:	Capecitabine
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	21-09-2006
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	EUCTR2006-004052-20-NL
CCMO	NL13743.018.06