MRI for Vulva carcinoma.

Published: 05-12-2008
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Compare clinical investigation with different high-resolution MR imaging protocols in the preoperative assessment of patients with vulva carcinoma.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Vulvovaginal disorders (excl infections and inflammations)
Study type	Observational invasive

Summary

ID

NL-OMON35276

Source
ToetsingOnline

Brief title
MRI for vulva carcinoma.

Condition

- Vulvovaginal disorders (excl infections and inflammations)

Synonym
vulva carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: MRI, optimization, vulva carcinoma

Outcome measures

Primary outcome

Tumor dimensions and sensitivity and specificity of determination of

locoregional invasion.

Secondary outcome

n.a.

Study description

Background summary

High-resolution MRI may provide valuable additional information in patients with vulva carcinoma, especially in regard to the surgical work-up.

Study objective

Compare clinical investigation with different high-resolution MR imaging protocols in the preoperative assessment of patients with vulva carcinoma.

Study design

Prospective pilot study.

Study burden and risks

Normally these patients receive a CT scan before the operation. When they participate to the study a MRI scan will be done in staed of a CT scan.

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

- Age >= 18 years
- Histologically-proven squamous cell carcinoma of the vulva
- Clinical planning includes radical local excision of vulva carcinoma
- informed consent

Exclusion criteria

- Tumor-urethra, tumor-anal canal, or tumor-vagina distance > 2 cm (these patients are excluded as the chance of locoregional invasion is too low)
- Contraindications for MRI (including claustrophobia, obesity preventing placement in MR scanner, metal in body, *)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2009
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	05-12-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	23-09-2010
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

No registrations found.

In other registers

Register	ID
CCMO	NL24742.078.08