# 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.

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|---|---|
| **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 |