

# The Morphogenetic unit on MRI

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Visualization of the MGU and it\*s borders on MRI scans of women without cervical cancer.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Reproductive neoplasms male malignant and unspecified
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON31312

### Source

ToetsingOnline

### Brief title

The Morphogenetic unit on MRI

### Condition

- Reproductive neoplasms male malignant and unspecified
- Cervix disorders (excl infections and inflammations)

### Synonym

not relevant

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W,european union

### Intervention

**Keyword:** Cervical cancer, Female pelvis, Morphogenetic unit, MRI

## Outcome measures

### Primary outcome

On subsequent transverse T2 weighted images identification of the (subperitoneale uterovaginal) morphogenetic unit: cervical fibrous stroma (low signal intensity) and the dorsally horseshoe-shaped ligamentous mesometrium, utero sacral ligament (intermediate - low signal intensity).

On subsequent T2 weighted transverse and coronal images distinction of the morphogenetic unit from the bladder, bladder mesenteries (vesico uterine ligament), ureters, main pelvic autonomic-nerve plexus and the mesorectum (bordered by low signal intensity mesorectal fascia).

### Secondary outcome

inter observer variability

intra observer variability

## Study description

### Background summary

According to an existing new theory, growth of a primary cervical carcinoma is restricted to an embryological predisposed area called the morphogenetic unit (MGU) for a long phase during malignant progression. Macroscopic, microscopic, and occult local tumour spread should be confined to the aforementioned area. The MGU and its borders have been identified in female embryos of different gestational ages. During the surgical procedure the surgeon has to identify the borders of the MGU, and operate according to them. In surgical practice, this has been looked upon as feasible. Furthermore, a bordering lamella between the different parts of the ligamentum vesico-uterina, which has parts that do and parts that do not belong to the MGU, has been described in the literature.

## Study objective

Visualization of the MGU and its borders on MRI scans of women without cervical cancer.

## Study design

Observational study.

A single MRI will be performed by a 3 Tesla MRI scanner. Images will be studied by two different radiologists to find a clearly recognizable bordering structure, using criteria that were defined on beforehand.

## Study burden and risks

The MRI scan itself has no known adverse effects when performed on people without contraindications.

Buscopan (i.m.) is frequently and according to protocols used for abdominal MRI scans. Side effects are seldom and/or moderately severe.

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

healthy (no pelvic pathology)

pre menopausal

### Exclusion criteria

medical history of pelvic surgery or pelvic pathology

(post) menopause

contra indications for MRI

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-08-2007

Enrollment: 15

Type: Anticipated

## Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

## 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	NL17823.058.07