

# Endometrial waves in women with suspected gynaecological malignancy

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Objective: Evaluate uterine contraction features (frequency, amplitude, direction, and coordination) using a dedicated speckle-tracking algorithm by 2D transvaginal ultrasound measurement in postmenopausal women presenting with vaginal bleeding or...

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

## Summary

### ID

NL-OMON51675

### Source

ToetsingOnline

### Brief title

WAVES Malignant

### Condition

- Reproductive neoplasms female malignant and unspecified
- Menopause related conditions

### Synonym

ovarian tumours, Postmenopausal bloodloss

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Catharina-ziekenhuis

**Source(s) of monetary or material Support:** GE Healthcare

## Intervention

**Keyword:** Ovarian tumours, Postmenopausal bloodloss, Uterine peristalsis

## Outcome measures

### Primary outcome

Primary endpoints:

The primary outcomes investigated were the following uterine contraction features on TVUS:

Frequency, in contractions per minute

Amplitude (unitless)

Direction, in median velocity (from Cervix to Fundus or Fundus to Cervix)

Coordination, unitless (via mean squared error, or cross correlation)

### Secondary outcome

Secondary endpoints:

- Histopathological diagnosis based on histopathological examination (benign vs. malignant)
- TNM classification of gynaecological malignancy if applicable
- 1-year survival and treatment outcomes
- Hormonal status

## Study description

### Background summary

It is known that uterine contractions are heavily influenced by hormonal activity and changes during the menstrual cycle in women of fertile age. Uterine contraction activity thus has different characteristics and behaviour in each phase of the menstrual cycle which correspond to varying hormone

levels. Furthermore, it is becoming generally accepted that women with benign uterine disorders experience abnormal uterine contractions. This includes women with intracavitary lesions such as endometrial polyps or placental remnants. After menopause, in concordance with loss of ovarian function and the eventual drop in gonadotrophic factors, uterine contractions are quiescent, with little to no contraction activity.

However, no data are available on uterine contractions in (pre)malignant conditions of the female genital tract. With this study we aim to study an objective characterisation of uterine contraction activity in women presenting with postmenopausal vaginal bleeding and ovarian tumours, and link this to clinical and pathological outcomes. We hypothesise that uterine contraction activity in women with gynaecological malignancies may play an important (but as yet unresearched) role in the development and behaviour of gynaecological malignancies.

## **Study objective**

Objective: Evaluate uterine contraction features (frequency, amplitude, direction, and coordination) using a dedicated speckle-tracking algorithm by 2D transvaginal ultrasound measurement in postmenopausal women presenting with vaginal bleeding or ovarian tumour

## **Study design**

Study design and setting:

Single-centre observational prospective cohort study carried out in the outpatient gynaecology department of the Catharina Hospital in Eindhoven, the Netherlands.

## **Study burden and risks**

The TVUS is part of the standard work-up at our clinic of patients presenting with the aforementioned symptoms, and thus poses no added risk.

## **Contacts**

### **Public**

Catharina-ziekenhuis

Michelangelolaan 2  
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NL

### **Scientific**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

### **Inclusion criteria**

Group 1:

- Age >18 years
- Postmenopausal: lack of menstrual cycle for >1 year
- Symptoms vaginal bleeding

Group 2:

- Age >18 years
- Diagnosis of ovarian tumour or mass

### **Exclusion criteria**

- Mental disability
- Significant language barrier
- History of hysterectomy
- Uterine anomalies (congenital or not congenital)
- Uterine pathologies (leiomyomas, adenomyosis, endometriosis)
- Caesarean section in the past,
- Endometrial ablation in the past,
- Presence of IUD

## **Study design**

## Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

## Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 14-06-2022

Enrollment: 150

Type: Actual

## Ethics review

Approved WMO

Date: 19-04-2022

Application type: First submission

Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date: 19-08-2024

Application type: Amendment

Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

## 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	NL80268.100.22