

## Evaluation of the Subjectively Perceived Pelvic Floor Function in Patients With Gynecological Tumors and Breast Cancer Under Systemic Tumor Therapy Using a Validated Questionnaire

**NCT-Nummer:**

[NCT04655066](#)

**Studienbeginn:**

April 2018

**Letztes Update:**

04.12.2020

**Wirkstoff:**

-

**Indikation (Clinical Trials):**

Pelvic Floor Disorders

**Geschlecht:**

Alle

**Altersgruppe:**

Erwachsene (18+)

**Phase:**

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**Sponsor:**

St. Josefs-Hospital Wiesbaden GmbH

**Collaborator:**

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### Studien-Informationen

**Brief Summary:**

The multimodal therapy of gynecological malignancies and breast cancer often leads to an impairment of the pelvic floor function. This has a major impact on the quality of life of cancer patients. The aim of the study is to record and analyze the potential subjective

impairment of the bladder, bowel and sexual function under systemic tumor therapy as well as possible influencing factors by means of validated disease-specific questionnaires. to find possible starting points for the prevention and treatment of the symptoms.

## Ein-/Ausschlusskriterien

### **Inclusion Criteria:**

- Breastcancer under tumor therapy
- Gynecological carcinoma under tumor therapy

### **Exclusion Criteria:**

- none

## Studien-Rationale

### **Primary outcome:**

1. Primary Endpoint (Time Frame - 12 months):

*The primary endpoint and basis for the sample size calculation is the incidence of clinically relevant deteriorations in the total score of pelvic floor function. Bladder function, bowel function, sedimentation problems and sexual function, QoL are recorded using scores using the validated German pelvic floor questionnaire*

### **Secondary outcome:**

1. Secondary Endpoint (Time Frame - 12 months):

*Type of tumor (breast cancer, ovarian cancer, cervical cancer, endometrial cancer, vulvar cancer), TNM stage, body weight, height, age, type of tumor therapy, number of previous therapies (chemoline), parity, mode of delivery, nicotine abuse, medication, previous surgery.*

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**Status: Rekrutierend**

*Quelle: [ClinicalTrials.gov](https://ClinicalTrials.gov)*