

## Analysis and Optimization of Predictive and Therapeutic Models in Uterine Neoplasms

**NCT-Nummer:**

[NCT03624712](#)

**Studienbeginn:**

Januar 2012

**Letztes Update:**

11.02.2020

**Wirkstoff:**

-

**Indikation (Clinical Trials):**

Neoplasms, Uterine Neoplasms

**Geschlecht:**

Frauen

**Altersgruppe:**

Erwachsene (18+)

**Phase:**

-

**Sponsor:**

University Hospital Tuebingen

**Collaborator:**

University Hospital Heidelberg, University of Homburg,

### Studien-Informationen

**Brief Summary:**

Evaluation of clinical, therapeutic and prognostic relevance of new experimental results as well as optimization of therapeutic models and development of a new algorithm for therapeutic plan and therapy in patients with uterine neoplasm

## Ein-/Ausschlusskriterien

### **Inclusion Criteria:**

- Confirmed uterine malignancy ( cervical cancer, endometrial cancer, sarcoma)
- If operable: surgical primary therapy: laparoscopic/robot-assisted or open radical gynecological surgery
- Written consent
- Willingness and ability to participate in all study-specific procedures
- Age  $\geq$  18 years

### **Exclusion Criteria:**

- Severe and acute general disease in the last 4 weeks
- Acute or chronic psychiatric disorders
- Other factors questioning study participation (e.g. acute psychosocial stress, insufficient understanding of nature and consequences of the study, inadequate skills of the German language)

## Studien-Rationale

### **Primary outcome:**

1. CTC and DTC analysis (Time Frame - 12 months):  
*Counting the number of tumor cells in blood and bone marrow*
2. HPV (Time Frame - 12 months):  
*Analysis of HPV types by DNA tests in peripheral blood, bone marrow, sentinel-lymph node, cervical-, endometrial- and myometrial-tissue, intraperitoneal wash fluid*
3. DNA (Time Frame - 12 months):  
*Determination of DNA in peripheral blood*
4. Douglas cytology (Time Frame - 12 months):  
*Intraperitoneal wash fluid*
5. Proteomic analysis (Time Frame - 12 months):  
*Analysis of proteins by mass spectrometry in removed uterine and sentinel lymph node tissue*
6. Sentinel lymph nodes (Time Frame - 12 months):  
*Number of detectable lymph nodes by Tc99m- and indocyanine green-labeling*
7. Peripheral nerve conduction velocity (Time Frame - 12 months):  
*Intra- and interindividual comparison of N. obturatorius, N. pudendus between pre and post radical*

*gynecological surgery*

8. Urodynamic- cystomanometry between pre an post radical gynecological surgeryuroflowmetry  
(Time Frame - 12 months):  
*pressur/volume relationship*

9. CTC and DTC analysis (Time Frame - 12 months):  
*Identification and quantification of genetic variants and mutations*

10. Urodynamic- urethral pressure profile between pre an post radical gynecological  
surgeryuroflowmetry (Time Frame - 12 months):  
*cm H2O*

11. Urodynamic- uroflowmetry between pre an post radical gynecological surgeryuroflowmetry  
(Time Frame - 12 months):  
*rate of flow of urine*

## Geprüfte Regime

- uterine neoplasms:  
*Analysis of circulating (CTC) and disseminating tumor cells (DTC), determination of Human Papilloma Virus (HPV), Douglas cytology, DNA analysis in blood, proteome analysis, sentinel lymph node detection*

## Studienlocations (1 von 1)

### **University Hospital Tuebingen, Department of Women's Health**

72076 Tuebingen  
(Baden-Württemberg)  
Germany

**Status: Rekrutierend**

Quelle: *ClinicalTrials.gov*