ISRCTN77165120 https://doi.org/10.1186/ISRCTN77165120

# Randomized phase III trial of paclitaxel plus topotecan versus topotecan plus cisplatin in recurrent or persistent cervical cancer stage IVb

| | | |
|---|---|---|
| **Submission date**<br>23/01/2006 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol |
| **Registration date**<br>15/05/2006 | **Overall study status**<br>Completed | [_] Statistical analysis plan<br>[_] Results |
| **Last Edited**<br>15/05/2006 | **Condition category**<br>Cancer | [_] Individual participant data<br>[_] Record updated in last year |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Prof Matthias W. Beckmann

**Contact details**
Universitaetsstr. 21-23
Erlangen
Germany
91054
+49 (0)9131 8533451
studienzentrale@gyn.imed.uni-erlangen.de

## Additional identifiers

**Protocol serial number**
IFG-01-0106

## Study information

**Scientific Title**

## Acronym
AGO-Uterus-9

## Study objectives
A chemotherapy scheme with topotecan and paclitaxel can be equally or more effective in advanced cervical cancer as a standard chemotherapy scheme

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Ethics approval details not yet received as of 15/05/2006

## Study design
Prospective, two-armed, randomised clinical therapy trial

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Advanced carcinoma of the cervix uteri

## Interventions
Patients are randomised to receive one of the following:
1. Paclitaxel and topotecan
2. Topotecan and cisplatin

## Intervention Type
Drug

## Phase
Phase III

## Drug/device/biological/vaccine name(s)
Paclitaxel, topotecan, cisplatin

## Primary outcome(s)
Overall-survival

## Key secondary outcome(s))
1. Time to progression
2. Efficacy
3. Therapy tolerance
4. Quality of life

## Completion date
31/01/2008

# Eligibility

### Key inclusion criteria
Patients with progressive histologically confirmed carcinoma of the cervic uteri and measurable disease (Response Evaluation Criteria in Solid Tumors [RECIST]) without treatment alternatives to chemotherapy

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
Female

### Key exclusion criteria
Bilateral hydronephrosis, central nervous system (CNS)-metastases or reduced general condition

### Date of first enrolment
01/02/2006

### Date of final enrolment
31/01/2008

# Locations

### Countries of recruitment
Germany

### Study participating centre
**Universitaetsstr. 21-23**
Erlangen
Germany
91054

# Sponsor information

### Organisation
Institute for Women’s Health (Institut fuer Frauengesundheit GmbH) (Germany)

### ROR

https://ror.org/01f30wv40

# Funder(s)

**Funder type**
Industry

**Funder Name**
Institute for Women’s Health budget supported by GlaxoSmithKline GmbH & Co. KG Germany

# Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration