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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
Overall-survival

Secondary outcome measures
1. Time to progression
2. Efficacy
3. Therapy tolerance
4. Quality of life

Overall study start date
01/02/2006

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

Age group
Adult

Sex
Female

Target number of participants
326

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)

Sponsor details
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Sponsor type
University/education

Website
http://www.ifg-erlangen.de

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration