

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/05/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 15/05/2006	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 cervix 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