

A randomised phase III trial of preoperative chemoradiation versus chemoradiation with weekly cisplatin/gemcitabine in FIGO stages IB2-IIB

Submission date 28/03/2005	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 06/06/2005	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 03/05/2019	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

004/009/OM

Study information

Scientific Title

A randomised phase III trial of preoperative chemoradiation versus chemoradiation with weekly cisplatin/gemcitabine in FIGO stages IB2-IIB

Study objectives

Cisplatin (with or without 5-FU) concurrent with radiation (external beam and brachytherapy) is the current standard of treatment. We have reported that the combination of cisplatin and gemcitabine is superior in terms of pathological complete response than cisplatin alone when used concurrent to pelvic radiation in IB2, IIA and IIB patients.

On the other hand, at least three phase II studies show that neoadjuvant or preoperative (before radical hysterectomy) chemoradiation yields a pathological response rate that exceeds 50% and as a whole the survival appears better than standardly treated with external beam and brachytherapy. Finally, in many centers and many countries brachytherapy equipment and/or human resources are not enough or do not exist at all, therefore patients receive extrafacial hysterectomy instead of brachytherapy.

Based on these facts we decided to perform a randomised phase III trial to compare radical hysterectomy versus brachytherapy after external beam radiation with the combination of cisplatin-gemcitabine in both arms (assuming the superiority of cisplatin gemcitabine versus cisplatin). The hypothesis being a superiority of the experimental arm of 10% in survival. The sample size has an alfa of 5% and beta of 80%.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cervical carcinoma

Interventions

Patients with non-small cell cervical carcinoma International Federation of Gynecology and Obstetrics (FIGO) staged as IB2, IIA and IIB will be randomized to either:

Arm 1: External Beam Radiation 50 Gy plus cisplatin at 40 mg/m² and gemcitabine 125 mg/m² weekly for six applications followed by standard low-dose rate brachytherapy with Cesium sources.

Arm 2: External Beam Radiation 50 Gy plus cisplatin at 40 mg/m² and gemcitabine 125 mg/m² weekly for six applications followed by radical hysterectomy with pelvic and para-aortic lymphadenectomy. Patients in this arm will receive adjuvant brachytherapy if surgical margins positive.

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Cisplatin and gemcitabine

Primary outcome(s)

Efficacy in terms of overall and progression free-survival

Key secondary outcome(s)

Toxicity of chemoradiation and early and late complications the surgical treatment.

Completion date

31/12/2006

Eligibility**Key inclusion criteria**

1. Histologically confirmed squamous, adenosquamous or adenocarcinoma
2. Untreated
3. International Federation of Gynecology and Obstetrics (FIGO) staged IB2, IIA and IIB
4. Mesurable disease
5. Aged 18 to 70 years
6. Zero to two World Health Organisation (WHO) status performance
7. Normal renal, hepatic and hematological function
8. Negative pregnancy test or biological inability to become pregnant
9. Informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Female

Total final enrolment

211

Key exclusion criteria

1. Systemic and/or uncontrolled disease that preclude the use of chemotherapy
2. Pre-existent or concurrent neuropathy of any cause
3. Mental disease
4. Previous malignancy except non-melanoma skin cancer

Date of first enrolment

01/09/2004

Date of final enrolment

31/12/2006

Locations

Countries of recruitment

Mexico

Study participating centre

Instituto Nacional de Cancerologia

Mexico City

Mexico

14080

Sponsor information

Organisation

National Cancer Institute of Mexico (Instituto Nacional de Cancerologia)

ROR

<https://ror.org/04z3afh10>

Funder(s)

Funder type

Government

Funder Name

National Cancer Institute of Mexico (Instituto Nacional de Cancerologia)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2013	03/05/2019	Yes	No