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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

Registration date
06/06/2005

Overall study status
Completed

Last Edited
03/05/2019

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Study design
Randomised controlled trial

Primary study design
Interventional

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/m^2 and gemcitabine 125 mg/m^2 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/m^2 and gemcitabine 125 mg/m^2 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