

LOROCSON study: Late Onset Recurrent Ovarian Cancer: Surgery Or Not

Submission date 20/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 20/12/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 13/10/2008	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
MEC 2005-128

Study information

Scientific Title

A randomised phase III study for the treatment of recurrent epithelial ovarian cancer: chemotherapy alone versus chemotherapy followed by secondary cytoreductive surgery in patients with a disease-free interval of more than 6 months

Acronym

LOROCSON

Study objectives

The median progression-free survival in the chemotherapy-alone arm is assumed to be 13 months. It is assumed that the addition of surgery increases the median progression-free survival with four months.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local medical ethics committee

Study design

Multicentre, randomised, active controlled, parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Ovarian cancer

Interventions

After registration the patient will immediately start the first course of chemotherapy. After the induction chemotherapy the response to therapy will be evaluated. In case of progressive disease the patient will go off treatment. The other patients will be randomised to either continuation of the chemotherapy without surgery (treatment A) versus secondary cytoreductive surgery followed by chemotherapy (treatment B).

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Progression-free survival.

Secondary outcome measures

1. Survival
2. Toxicity
3. Surgical treatment related complications
4. Quality of life

Overall study start date

01/10/2005

Completion date

01/10/2010

Eligibility**Key inclusion criteria**

1. Recurrence of epithelial ovarian cancer
2. After first line chemotherapy with a disease-free interval of at least 6 months
3. Aged greater than 18 years
4. World Health Organization (WHO) Performance Status 0 - 2
5. First-line therapy should have consisted of at least four courses of either cisplatin or carboplatin

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

700

Key exclusion criteria

1. More than one line chemotherapy
2. Complete bowel obstruction
3. Metastasised carcinoma (other tumour)
4. Leptomeningeal or brain metastases

Date of first enrolment

01/10/2005

Date of final enrolment

01/10/2010

Locations

Countries of recruitment

Netherlands

Study participating centre

Erasmus Medical Center

Rotterdam

Netherlands

3015 GJ

Sponsor information

Organisation

Erasmus Medical Centre (The Netherlands)

Sponsor details

Department of Obstetrics and Gynecology

Dr. Molewaterplein 60

Rotterdam

Netherlands

3015 GJ

Sponsor type

Hospital/treatment centre

Website

<http://www.erasmusmc.nl/content/englishindex.htm>

ROR

<https://ror.org/018906e22>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Erasmus Medical Centre (The Netherlands)

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