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

Submission date	Recruitment status	[ ] Prospectively registered
20/12/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/12/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
13/10/2008	Cancer	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr P.M.L.H. Vencken

Contact details
Erasmus Medical Center
Department Obstetrics and Gynecology
Dr. Molewaterplein 60
Rotterdam
Netherlands
3015 GJ
+31 (0)10 463 6363
p.vencken@erasmusmc.nl

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