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Lymphadenectomy in ovarian neoplasms

Submission date
09/10/2008

Registration date
23/10/2008

Last Edited
10/04/2019

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Ovarian cancers are classed as advanced when the cancer has spread away from the ovary to other parts of the body, such as the lymph nodes. Lymphadenectomy is a surgical procedure that it is often carried out as part of cancer treatment to remove groups of lymph nodes (e.g., the pelvic and para-aortic lymph nodes). The aim of this study is to assess the effectiveness of pelvic and para-aortic lymphadenectomy in patients with advanced ovarian cancer, in terms of its safety and its effects on patient survival and quality of life.

Who can participate?
Women aged 18-75 with advanced ovarian cancer

What does the study involve?
Participants are randomly allocated to one of two groups. One group undergoes standard surgery for advanced ovarian cancer, while the other group undergoes standard surgery and lymphadenectomy. Patient survival, quality of life and complications are assessed in the two groups.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Philipps-University of Marburg (Germany)

When is the study starting and how long is it expected to run for?
October 2008 to December 2017

Who is funding the study?
German Research Council (Deutsche Forschungsgemeinschaft [DFG]) (Germany)

Who is the main contact?
Prof Uwe Wagner

Contact information

Type(s)
Scientific

Contact name
Prof Uwe Wagner

Contact details
Klinik für Gynäkologie
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00712218

Secondary identifying numbers
AGO-Ovar OP.3

Study information

Scientific Title
Lymphadenectomy in ovarian neoplasms

Acronym
LION

Study objectives
The primary study objective is to assess the efficacy of systematic pelvic and para-aortic lymphadenectomy in patients with advanced ovarian cancer and intra-abdominal complete debulking with respect to overall survival.

Secondary objectives are the safety of systematic pelvic and para-aortic lymphadenectomy in these patients and the effect of systematic lymphadenectomy on progression-free survival (PFS) and quality of life (QoL).

A further objective is to explore the association of number of resected lymph nodes and primary and secondary outcome measures.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of the Philipps-University of Marburg, 11/08/2008, ref: AZ 115/08

Study design
Open randomised prospective multicentre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Ovarian cancer

Interventions
Control group: standard surgery
Intervention group: standard surgery + lymphadectomy

Intervention Type
Procedure/Surgery

Primary outcome measure
Overall survival. Time frame: time from randomisation until death.

Secondary outcome measures
1. Progression-free survival (PFS). Time frame: Progression-free survival time is calculated from the date of surgery until the date of first progressive disease or death, whichever occurs first or date of last contact.
2. Quality of life (QoL) as measured by European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire for Cancer patients (EORTC QLQ-C30), OV28 at baseline, Day 7-21 after surgery, at Visit 2 (within 6 weeks after end of primary chemotherapy or 6 months after surgery, whichever occurs first), 6 months after chemotherapy
3. Number of resected lymph nodes. Time frame: intra operative
4. Complications. Time frame: intra operative, 60 days after surgery

Overall study start date
23/10/2008

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1. Primary diagnosis of invasive epithelial ovarian cancer, Federation of Obstetricians and Gynaecologists (FIGO) stage IIB-IV (IV only if resectable metastasis in pleura, liver, spleen, and/or abdominal wall)
2. Macroscopic complete resection
3. Age 18-75 years
4. Patients who have given their signed and written informed consent
5. Good performance status (Eastern Cooperative Oncology Group [ECOG] 0/1)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Female

Target number of participants
640

Key exclusion criteria
1. Non epithelial ovarian malignancies and borderline tumours
2. Intraoperative clinically suspicious lymph nodes (bulky nodes)
3. Secondary invasive neoplasms in the last 5 years (except synchronal endometrial carcinoma FIGO IA G1/2, non melanoma skin cancer, breast cancer T1 N0 M0 G1/2) or with any signs of relapse or activity
4. Recurrent ovarian cancer
5. Prior chemotherapy for ovarian cancer or abdominal/pelvic radiotherapy
6. Diseases of the lymph system (including lymph oedema of unknown origin)
7. Clinically relevant dysfunctions of blood clotting (including medicamentous conditioned reasons, e.g., ASS, if not stopped at least 7 days prior to surgery)
8. Any significant medical reasons, age or performance status that contraindicate the study procedures (in the opinion of investigator)
9. Prior retroperitoneal lymph node dissection (systematic or sampling)
10. Pregnancy
11. Those who suffer from dementia or significantly altered mental status, and therefore, are unable to understand the trial details and give informed consent
12. Any reasons interfering with regular follow-up

Date of first enrolment
23/10/2008

Date of final enrolment
31/12/2017

Locations

Countries of recruitment
Germany

Study participating centre
Klinik für Gynäkologie
Marburg
Germany
35032

Sponsor information

Organisation
Philipps-University of Marburg (Germany)

Sponsor details
Robert-Kochstr. 5
Marburg
Germany
35037

Sponsor type
University/education

Website
http://www.kks-mr.de

ROR
https://ror.org/01rdrb571

Funder(s)

Funder type
Government

Funder Name
Deutsche Forschungsgemeinschaft (ref: GZ: WA 740/4-1)

Alternative Name(s)
German Research Association, German Research Foundation, DFG

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	28/02/2019	10/04/2019	Yes	No