ISRCTN87786644 https://doi.org/10.1186/ISRCTN87786644

A randomised trial in relapsed ovarian cancer, early treatment based on Cancer Antigen (CA) 125 levels alone versus delayed treatment based on conventional clinical factors

Submission date
06/04/2000

Recruitment status
No longer recruiting

Registration date
06/04/2000

Overall study status
Completed

Last Edited
22/10/2018

Condition category
Cancer

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

Plain English summary of protocol
http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=21

Study website
http://www.ctu.mrc.ac.uk/studies/documents/OV05v21.pdf

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00002895

Secondary identifying numbers
OV05

Study information

Scientific Title
A randomised trial in relapsed ovarian cancer, early treatment based on Cancer Antigen (CA) 125 levels alone versus delayed treatment based on conventional clinical factors

Study objectives
To investigate the benefit of early chemotherapy for recurrent ovarian cancer based on a raised CA125 (a serum marker) level alone, versus chemotherapy based on conventional clinical indicators. The policies will be compared in terms of overall survival, quality of life and health economics.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London MREC approval

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Cancer

Interventions
Patients are initially registered onto the trial. Following a raised CA125 result patients are randomised to receive either delayed treatment until patient shows clinical signs of relapse or immediate treatment which must start within 4 weeks.
All patients will be followed until death at 3 monthly visits.

Intervention Type

Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
CA125 (a serum marker)

Primary outcome measure
Survival time

Secondary outcome measures
1. Quality of life
2. Health Economics

Overall study start date
26/05/1996

Completion date
31/12/2005

Eligibility

Key inclusion criteria
1. Histologically confirmed epithelial ovarian, fallopian tube or serous primary peritoneal carcinoma
2. In complete remission with a normal CA125 since first-line platinum containing chemotherapy
3. A normal CA125 result within 4 weeks of registration onto the trial
4. Patient in confirmed remission (based on physical gynaecological examination) within 6 weeks of registration onto the trial
5. Able to attend regular follow-up and have regular blood tests
6. Local laboratory able to blind CA125 results from clinicians
7. No concomitant or previous malignancy within 5 years which is likely to interfere with the protocol treatments or comparisons, except with concomitant or previous non-melanoma skin cancer
8. Informed consent from the patient

Participant type(s)
Patient

Age group
Not Specified

Sex
Female

Target number of participants
1400 - closed to recruitment and in long-term follow-up

Key exclusion criteria

Previous malignancy within 5 years

Date of first enrolment
26/05/1996

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
Austria

Belgium

England

France

Ireland

Italy

Netherlands

Portugal

Russian Federation

South Africa

Spain

United Kingdom

Study participating centre
MRC Clinical Trials Unit
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
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W1B 1AL
+44 (0)20 7636 5422
clinical.trial@headoffice.mrc.ac.uk

Sponsor type
Research council

Website
http://www.mrc.ac.uk

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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?
Plain English results				No	Yes
Results article	results	02/10/2010		Yes	No