

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/04/2000	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 22/10/2018	Condition category Cancer	<input type="checkbox"/> 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

Contact name

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Contact details

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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

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London
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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