

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

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00002895

Protocol serial number

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

Study type(s)

Other

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(s)

Survival time

Key secondary outcome(s)

1. Quality of life
2. Health Economics

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Female

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

United Kingdom

England

Austria

Belgium

France

Ireland

Italy

Netherlands

Portugal

Russian Federation

South Africa

Spain

Study participating centre

MRC Clinical Trials Unit

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

Medical Research Council (MRC) (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, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

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	02/10/2010		Yes	No
Plain English results				No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes