ISRCTN11916376 https://doi.org/10.1186/ISRCTN11916376

International Collaborative Ovarian Neoplasm studies (1): A trial of adjuvant chemotherapy for early-stage ovarian cancer

Submission date 06/04/2000	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 06/04/2000	**Overall study status** Completed	
Last Edited 31/12/2021	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00002477

Secondary identifying numbers

ICON1

Study information

Scientific Title
International Collaborative Ovarian Neoplasm studies 1 (ICON1): A trial of adjuvant chemotherapy for early-stage ovarian cancer

Acronym
ICON1

Study objectives
Currently it is not known whether adjuvant chemotherapy is of any benefit in ovarian cancer, and all previous trials have been too small to give reliable evidence. The prognosis for early disease is much better than for advanced disease, which is known to respond to platinum-based chemotherapy, and a similar response in early disease would prolong the lives of many thousands of women each year. However, any benefit must be weighed against the toxicity associated with the treatment employed, and hence reliable evidence regarding the size of any benefit to adjuvant treatment is needed.

The aim of the study was to compare immediate with deferred chemotherapy in patients with early stage epithelial ovarian cancer

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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

Interventions

Immediate chemotherapy or chemotherapy deferred until indicated

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Survival time; recurrence-free survival.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1991

Completion date
21/01/2000

Eligibility

Key inclusion criteria
1. Chemotherapy not clearly indicated
2. No previous malignancy
3. No prior radiotherapy or chemotherapy
4. No contraindication to chemotherapy

Participant type(s)
Patient

Age group
Not Specified

Sex
Female

Target number of participants
2000

Total final enrolment
477

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/1991

Date of final enrolment

21/01/2000

Locations

Countries of recruitment
England

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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Sponsor type
Research council

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

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (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
Not provided at registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications		01/11/2001		Yes	No
Other publications		15/01/2003		Yes	No
Other publications		01/11/2003		Yes	No
Other publications		01/11/2003		Yes	No
Abstract results	Long-term follow-up	20/06/2007	31/12/2021	No	No