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A randomised, two-arm, multicentre Gynaecologic Cancer InterGroup trial of adding bevacizumab to standard chemotherapy (carboplatin and paclitaxel) in patients with epithelial ovarian cancer

Submission date 29/11/2005	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/01/2006	**Overall study status** Completed	
Last Edited 05/02/2019	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.icon7trial.org

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2005-003929-22

IRAS number

ClinicalTrials.gov number
NCT00483782

Secondary identifying numbers
ACTRN12607000188437

Study information

Scientific Title
A randomised, two-arm, multicentre Gynaecologic Cancer InterGroup trial of adding bevacizumab to standard chemotherapy (carboplatin and paclitaxel) in patients with epithelial ovarian cancer

Acronym
ICON7

Study objectives
To evaluate the efficacy and safety of adding bevacizumab to carboplatin and paclitaxel in patients with epithelial ovarian cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London MREC, 14/09/2006

Study design
Randomised (1:1 basis) two-arm multicentre open-label phase III study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Patient information can be found on the website at http://www.icon7trial.org

Health condition(s) or problem(s) studied

Epithelial ovarian cancer

Interventions
Control arm: carboplatin plus paclitaxel on day 1 every 3 weeks until disease progression or for a maximum of 6 cycles
Research arm: carboplatin plus paclitaxel on day 1 every 3 weeks until disease progression or for a maximum of 6 cycles, with bevacizumab on day 1 every 3 weeks until disease progression or for a maximum of 18 cycles

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Bevacizumab, carboplatin, paclitaxel

Primary outcome measure
Progression-free survival (PFS)

Secondary outcome measures
1. Overall survival (OS)
2. Response rate
3. Duration of response
4. Toxicity
5. Quality of life (QoL)
6. Health economics
7. Translational (biomarker) research

Overall study start date
01/10/2006

Completion date
31/10/2008

Eligibility

Key inclusion criteria
1. Written informed consent and able to comply with the protocol
2. Histologically confirmed:
2.1. High risk International Federation of Gynaecology and Obstetrics (FIGO) stage I and II a, with grade 3 or clear cell histology, epithelial ovarian cancer
2.2. FIGO stage IIb - IV (all grades, all histological types) epithelial ovarian cancer
2.3. Fallopian tube or primary peritoneal cancer
3. Patients fit enough to receive protocol treatment
4. Urine dipstick for proteinuria less than 2+ (if urine dipstick is greater than or equal to 2+, 24 hour urine must demonstrate less than or equal to 1 g of protein)

Participant type(s)

Patient

Age group
Adult

Sex
Female

Target number of participants
1,520

Key exclusion criteria
1. Surgery (including open biopsy), or radiotherapy within the last 4 weeks prior to first dose of bevacizumab or anticipation of interval cytoreductive surgery during study treatment
2. Malignancies other than ovarian cancer within 5 years prior to randomisation, except for adequately treated carcinoma in situ of the cervix and/or basal cell skin cancer
3. Uncontrolled hypertension
4. Current or recent (within 10 days of first dose of study treatment) use of aspirin greater than 325 mg/day
5. Current or recent (within 10 days prior to study treatment start) use of full-dose oral or parenteral anticoagulants or thrombolytic agent for therapeutic purposes (except for line patency)

Date of first enrolment
01/10/2006

Date of final enrolment
31/10/2008

Locations

Countries of recruitment
Australia

Canada

Denmark

England

Finland

France

Germany

New Zealand

Norway

Sweden

United Kingdom

Study participating centre
CRUK Clinical Centre in Leeds
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation
Medical Research Council (UK)

Sponsor details
222 Euston Road
London
United Kingdom
NW1 2DA

Sponsor type
Research council

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

ROR
https://ror.org/03x94j517

Funder(s)

Funder type
Industry

Funder Name
F. Hoffman-La Roche

Alternative Name(s)
Hoffman-La Roche, F. Hoffmann-La Roche Ltd.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Switzerland

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	29/12/2011		Yes	No
Results article	results	01/08/2015		Yes	No
Results article	cost-effectiveness results	01/06/2016		Yes	No
Results article	exploratory outcome results	01/01/2019	05/02/2019	Yes	No