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

Plain English summary of protocol

Not provided at time of registration

Study website

http://www.icon7trial.org

Contact information

Type(s)

Scientific

Contact name

Dr Tim Perren

Contact details

CRUK Clinical Centre in Leeds St James's University Hospital Beckett Street Leeds United Kingdom LS9 7TF +44 (0)113 206 4670 t.j.perren@leeds.ac.uk

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 Plain English results	Details	Date created	Date added	Peer reviewed? No	Patient-facing? 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