

Sequential schedule of platinum then paclitaxel-based chemotherapy for women with epithelial non-mucinous advanced inoperable peritoneal malignancy

Submission date 17/10/2006	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 14/12/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/03/2020	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

<http://www.cancerhelp.org.uk/trials/a-trial-looking-at-chemotherapy-before-and-after-surgery-for-advanced-peritoneal-cancer>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

2005-001875-37

IRAS number

ClinicalTrials.gov number
NCT00838656

Secondary identifying numbers
OV2039; AK/RH/22498/1

Study information

Scientific Title

A randomised feasibility study of extended chemotherapy with neoadjuvant carboplatin, then surgery followed by adjuvant paclitaxel and gemcitabine versus neoadjuvant gemcitabine and carboplatin, then surgery, followed by adjuvant paclitaxel for women with epithelial non-mucinous advanced inoperable peritoneal malignancy

Acronym

Neo-Escape

Study objectives

1. Up to 12 cycles of chemotherapy in a six plus six sequential schedule of platinum then paclitaxel based chemotherapy are tolerable and feasible for most patients.
2. The addition of gemcitabine to either carboplatin induction or the paclitaxel consolidation /adjuvant phase may enhance the overall activity of such a sequential schedule.

On 23/06/2009 this record was updated. All updates can be found under the relevant section with the above update date. Please also note that at this time, the overall trial end date was updated; the initial end date at the time of registration was 01/03/2009.

On 15/02/2011 the overall trial end date was extended from 31/03/2011 to 30/09/2011.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Warwickshire Research Ethics Committee, 06/08/2007, ref: 07/Q2803/73

Study design

Randomised two-arm feasibility study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Advanced, inoperable ovarian cancer (epithelial non-mucinous advanced inoperable peritoneal malignancy)

Interventions

Group one: six cycles of chemotherapy with neoadjuvant carboplatin, then surgery, followed by six cycles of adjuvant paclitaxel and gemcitabine
Group two: six cycles of neoadjuvant gemcitabine and carboplatin, then surgery, followed by six cycles of adjuvant paclitaxel

On 23/06/2009 this record was updated to include a new sponsor; the initial sponsor at the time of registration was the University of Birmingham (UK).

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Carboplatin, paclitaxel and gemcitabine

Primary outcome measure

The percentage of patients completing 12 cycles of chemotherapy in each study arm, considered separately.

Secondary outcome measures

1. Toxicities
 2. Quality of life
 3. Objective response rate to the induction phase of chemotherapy (first six cycles) assessed on Computed Tomography (CT), clinically, at surgery, and using CA-125 tumour marker
 4. Objective response rate following all 12 (six plus six) cycles of treatment, assessed clinically, on CT and using CA-125
 5. Progression-free and overall survival, particularly at 34 weeks (end of treatment)
- These will be assessed separately for each treatment arm.

Overall study start date

01/03/2007

Completion date

25/05/2011

Eligibility

Key inclusion criteria

1. Clinical, radiological, histological and findings consistent with a diagnosis of International Federation of Gynecology and Obstetrics (FIGO) stage 3C/4 primary epithelial ovarian cancer, primary peritoneal carcinoma, ovarian carcinosarcoma, or fallopian tube carcinoma
2. Patients (aged 18 - 75 years) will be unsuitable for primary debulking surgery as defined by laparoscopic staging procedures, supplemented by clinical and radiological assessments
3. Eastern Cooperative Oncology Group (ECOG) performance status zero, one, two or three

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

75 Years

Sex

Female

Target number of participants

88

Key exclusion criteria

1. Prior malignancy, chemotherapy or radiotherapy
2. Known brain metastases
3. Poorly controlled potentially serious medical conditions likely to render treatment compliance with the protocol difficult
4. Those of child-bearing potential not employing adequate contraception, which may include prescription contraceptives

Date of first enrolment

03/12/2007

Date of final enrolment

25/05/2011

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

University Hospital Coventry
Coventry
United Kingdom
CV2 2DX

Sponsor information

Organisation

University of Warwick (UK)

Sponsor details

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Sponsor type

University/education

Website

<http://www2.warwick.ac.uk/>

ROR

<https://ror.org/01a77tt86>

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK (CRUK) (UK) - Clinical Trials Advisory and Awards Committee (CTAAC) (ref: C1582/A5678)

Alternative Name(s)

CR_UK, Cancer Research UK - London, CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

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
Abstract results	abstract	20/05/2012		No	No