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

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered			
17/10/2006		Protocol			
Registration date	Overall study status Completed	Statistical analysis plan			
14/12/2006		[X] Results			
Last Edited	Condition category	[] Individual participant data			
19/03/2020	Cancer				

## 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

Clinical Trials Information System (CTIS)

2005-001875-37

## ClinicalTrials.gov (NCT)

NCT00838656

#### Protocol serial number

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 intial 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

## Study type(s)

Treatment

## 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(s)

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

## Key secondary outcome(s))

- 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.

## 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

## Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Upper age limit

75 years

#### Sex

Female

#### 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

United Kingdom

England

# Study participating centre University Hospital Coventry

Coventry United Kingdom CV2 2DX

# Sponsor information

#### Organisation

University of Warwick (UK)

**ROR** 

# 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, Cancer Research UK (CRUK), CRUK

#### **Funding Body Type**

Private sector organisation

## **Funding Body Subtype**

Other non-profit organizations

#### Location

**United Kingdom** 

## **Results and Publications**

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

## **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	abstract	20/05/2012		No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results				No	Yes