ISRCTN24742183 https://doi.org/10.1186/ISRCTN24742183

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

Registration date
14/12/2006

Overall study status
Completed

Last Edited
19/03/2020

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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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

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, 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
Plain English results				No	Yes