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A pilot randomised controlled trial to evaluate the utility and efficacy of neutral argon plasma (PlasmaJet®) as a new technology in achieving complete debulking of advanced Epithelial Ovarian Cancer

Submission date 15/05/2014	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 27/05/2014	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 19/02/2019	**Condition category** Cancer	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol

Background and study aims:
Surgery for ovarian cancer involves the removal of pelvic organs (the womb, fallopian tubes and ovaries), abdominal organs (the omentum and the appendix) and any other tissues that may have been affected. The more of the cancer that is removed, the greater the time between the surgery and the cancer coming back and the longer the patient will survive with the disease. Removing all visible signs of a cancer, however, is not easy. The disease is often advanced and widespread and some tumours will be located in sensitive areas such as the surface of the bowel, diaphragm and other important internal structures. In this study, doctors will use a new technology the PlasmaJet to remove tumours that are found in these sensitive areas. The PlasmaJet uses a jet of neutral argon plasma to vaporise the tumours. The PlasmaJet has been used in other areas of medicine, such as sealing bleeding tissue (coagulation) and burning away thin layers of tissue (ablation) but this is the first study that will look at the effects of this technology in ovarian cancer surgery.

Who can participate?
Women with stage III ovarian cancer, that is, with tumours in at least one ovary and where there is evidence that the disease has spread to the abdomen (confirmed peritoneal metastasis outside the pelvis). Patients have to be well enough to cope with the treatment and written consent is obtained in all cases.

What does the study involve?
The study will involve assessing how well the neutral argon plasma (PlasmaJet) technology performs in removing (vapourising) tumours during surgery for ovarian cancer.

What are the possible benefits and risks of participating?
There may not be any immediate benefit to the participants, however the working hypothesis is that it might be safer and faster to debulk ovarian cancer with the PJ device.

Where is the study run from?
Royal Surrey County Hospital, Guildford, UK

When is the study starting and how long is it expected to run for?
March 2013 until the end of December 2017.

Who is funding the study?
GRACE, Department of Gynaecological Oncology, The Royal Surrey County Hospital NHS Foundation Trust, UK

Who is the main contact?
Dr Kavitha Madhuri
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
2014-002103-24

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PJEOC

Study information

Scientific Title

A pilot, randomised single blind study to evaluate the utility and efficacy of neutral argon plasma as a new technology in achieving complete cytoreduction of advanced epithelial ovarian carcinoma - initial feasibility study

Acronym
PJEOC

Study objectives
To evaluate the ability of PJ to achieve optimal cytoreduction (nil visible disease) in women undergoing open debulking surgery for EOC.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Committee - South East Coast (Surrey), 04/12/2012, ref: 12/LO/1229

Study design
Pilot, randomised single blind 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 (Stage 3/4) Epithelial Ovarian Cancer

Interventions
This is a initial feasibility pilot RCT. Each participant may be randomised to PJ vs No PJ at the time of their debulking surgery. Each participant will then be followed up for at least the next 5 years.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The primary outcome measure is the ability to achieve complete cytoreduction (nil macroscopic residual). To evaluate the ability of PJ to achieve optimal cytoreduction (nil visible disease) in women undergoing open debulking surgery for EOC

Secondary outcome measures
1. To explore if achieving optimal cytoreduction helps increase disease free interval and hence improve survival
2. To categorise the histopathological effects of the depth of tumour destruction of metastatic EOC using the PJ
3. Evaluate the depth of tissue damage caused with a range of power settings and interaction times in vitro following surgery
4. To document the side-effect profile post-operatively following extensive surgery
5. Collate patient reported outcome measures using a validated tool

Overall study start date
01/03/2013

Completion date
30/12/2017

Eligibility

Key inclusion criteria
1. Imaging+/- Clinical +/- laparoscopic e/o pelvic mass and metastatic disease (FIGO III/IV disease) at presentation
2. Confirmation of malignancy on histological/cytological criteria
3. All women aged 18 or over with newly diagnosed FIGO stage III to Stage IV EOC undergoing surgical treatment
4. All women fit to undergo treatment
5. No synchronous malignancy likely to interfere with comparisons
6. Written and informed patient consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
150

Key exclusion criteria

1. Patient choice
2. Patient unfit for any treatment modality
3. Patients who are medically unfit for surgery and would only be suitable for chemotherapy

Date of first enrolment
01/03/2013

Date of final enrolment
30/12/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Dept. of Gynaecological Oncology
Guildford
United Kingdom
GU2 7XX

Sponsor information

Organisation
Royal Surrey County Hospital NHS Foundation Trust (UK)

Sponsor details
c/o Cathy Mayes
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/050bd8661

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
GRACE, Department of Gynaecological Oncology, The Royal Surrey County Hospital, UK

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?
HRA research summary			28/06/2023	No	No