

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

Department of Gynaecological Oncology

Royal Surrey County Hospital, Guildford, UK

Contact information

Type(s)

Scientific

Contact name

Dr Kavitha Madhuri

Contact details

Dept. of Gynaecological Oncology

Royal Surrey County Hospital NHS Foundation Trust

Guildford

United Kingdom

GU2 7XX

Additional identifiers

Clinical Trials Information System (CTIS)

2014-002103-24

Protocol serial number

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

Primary study design

Interventional

Study design

Pilot, randomised single blind study

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Female

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

United Kingdom

England

Study participating centre

Dept. of Gynaecological Oncology
Guildford
United Kingdom
GU2 7XX

Sponsor information

Organisation

Royal Surrey County Hospital NHS Foundation Trust (UK)

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

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