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An investigation into the possible benefits to the reduction of lymph drainage following groin surgery for treatment of vulvar cancer using a new device (PlasmaJet) during surgery

Submission date
11/02/2019

Recruitment status
No longer recruiting

Registration date
19/02/2019

Overall study status
Completed

Last Edited
22/02/2019

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
When lymph nodes are removed from the female groin area as part of treatment for vulval cancer, occasionally collections of fluid (lymph) can occur in the area where the lymph nodes were present. These collections are called lymphocysts. In most cases they eventually get absorbed and resolve by themselves but occasionally they need to be drained repeatedly with needles over a period of few weeks.
Groin lymphocyst formation occurs in aprroximately 10% patients undergoing surgery for vulval cancer and all problems including wound infections, breakdown of wounds occur in nearly 50% of cases. It can cause physical symptoms like pain, swelling around the groin area, leaking of lymph fluid and infections. It is emotionally very distressing for the patient requiring frequent hospital attendances and treatment.
PlasmaJet® is a new device which has been reported to reduce the formation of lymph in surgical wounds and we would like to investigate its usefulness in reducing the chance of groin lymphocyst formation and other complications if it is used in the surgery to remove the lymph glands.
The aim of our study is to assess the potential and safety of using The PlasmaJet technology in the prevention of groin lymphocyst (collection of lymph fluid in the groin) formation by sealing tissues or to burn away thin layers of tissue in patients undergoing BGND for vulval cancer.

Who can participate?
Women over the age of 18 with a confirmed diagnosis of vulvar cancer and requiring removal of lymph glands on both sides of their groins are eligible to participate

What does the study involve?
Each patient will have one side of their groin treated with standard surgery and the other side will be treated using standard surgery followed by the PlasmaJet device.

What are the possible benefits and risks of participating?
The study is exploring if the PlasmaJet device offers any benefit in terms of reduction in the number of complications. The device is known to be safe and there are no known risks from participation.

Where is the study run from?
The Royal Surrey County Hospital NHS Foundation Trust in Guildford, Surrey.

When is the study starting and how long is it expected to run for?
August 2013 to August 2016

Who is funding the study?
The study is being supported by “GRACE” charity (https://www.grace-charity.org.uk/)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

PJBGND

Study information

Scientific Title
A prospective, randomised, crossover, feasibility study to evaluate the utility and efficacy of PlasmaJet as a new technology to assist in the management of lymphedema and lymphocyst formation by improving drainage of lymphatic fluid (lymphostasis) and coagulation (haemostasis) in patients undergoing bilateral groin node dissection (BGND) for vulval cancer.

Acronym
PJBGND

Study objectives
To evaluate the ability of PJ to reduce complications in women undergoing groin node dissection for vulvar cancer

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/01/2009, Surrey Research Ethics Committee (Royal Surrey County Hospital, GU2 7XX; 0207 1048058, NRESCommittee.SECoast-Surrey@nhs.net), ref: 09/H1109/71

Study design
Pilot randomised crossover study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Women with vulvar cancer undergoing groin node dissection

Interventions
The PlasmaJet device is used following groin node dissection on the side randomised to receive it (as per
protocol specifications)

Intervention Type
Device

Primary outcome measure
The feasibility of a crossover (split body) double-blind RCT using an interventional device (PJ) in women undergoing BGND for vulvar cancer surgery. Measured by the number of patients recruited, number of patients declining participation and reason for decline if any exists. Assessed at end of study.

Secondary outcome measures
1. The potential and safety of the PJ device in the prevention of groin lymphocyst formation by prophylactic coagulation of lymph vessels in patients undergoing BGND for vulval cancer, recorded daily in patient records
2. The side-effect profile post-operatively following surgery with the PJ device. Recorded in the operating notes and post-operatively in the patient records
3. Wound infection rates, recorded daily in patient records while in hospital and in the clinic notes following discharge till the wound has healed completely.
3. Hospital readmission rates, recorded daily in patient records while in hospital and in the clinic notes following discharge till the wound has healed completely.
4. Lymphoedema rates, recorded at every clinic visit for 2 years following last patient recruitment.

Overall study start date
01/07/2013

Completion date
01/07/2017

Eligibility

Key inclusion criteria
1. Due to undergo BGND during their treatment pathway for histologically confirmed vulval cancer
2. Willing and able to provide informed consent
3. Aged 18 years or above
4. Willing to allow General Practitioner and other health care professionals, if appropriate, to be notified of participation in the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
25

Key exclusion criteria
1. Women with vulval cancer who do not undergo BGND
2. Previous groin surgery
3. Previous radiotherapy to the pelvic area including the groins
4. Pregnant, lactating or planning pregnancy during the course of the study
5. Not willing to participate

Date of first enrolment
01/01/2013

Date of final enrolment
01/01/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Surrey County Hospital NHS Foundation Trust
Egerton Road
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Sponsor information

Organisation
Royal Surrey County Hospitals NHS Foundation Trust

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Sponsor type

Hospital/treatment centre

ROR
https://ror.org/050bd8661

Funder(s)

Funder type
Charity

Funder Name
GRACE Charity

Results and Publications

Publication and dissemination plan
The study will be published in high-impact peer-reviewed medical journals by 01/07/2019. In view of the small number of participants, each patient will be contacted and offered an opportunity to discuss the results.
GRACE is scheduling a focus group of patients and we also have plans to disseminate the overview of findings in the local newspapers

Intention to publish date
01/07/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary
Available on request