

Feasibility Study to Investigate the Effect of Compression Stockings in the development of Lymphoedema following Treatment of Vulval Cancer

Submission date 29/09/2006	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 29/09/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 15/08/2012	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

N0009176682

Study information

Scientific Title

Study objectives

How practical and acceptable is the early use of compression stockings in vulval cancer patients after receiving treatment?

This is a pilot study to investigate the feasibility of the early use of Compression Stockings in reducing the incidence and severity of lymphoedema after treatment of vulval cancer. The findings are to be used to develop a future randomised controlled trial which will be a multicentre national study.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Cancer: Vulval

Interventions

Our hypothesis is that the use of compression stockings soon after treatment for vulval cancer is acceptable to patients and is worthy of investigation in the prevention of systematic lymphoedema in the form of a randomised controlled trial.

Participants will be randomised using sealed envelopes into two groups: either to wear compression stockings for 6 months starting within 3 days of cancer treatment (treatment group) or not to wear them (control group). Participants in both groups will receive all the usual treatment of vulval cancer including on leg care (otherwise known as Best Supportive Care).

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Feasibility and acceptability of applying compression stockings.

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/01/2012

Eligibility

Key inclusion criteria

20 Patients diagnosed with vulvar cancer of at least FIGO stage 1A.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Female

Key exclusion criteria

All patients diagnosed with vulvar cancer greater than stage 1A.

Date of first enrolment

29/12/2005

Date of final enrolment

01/01/2012

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Gateshead Health NHS Foundation Trust

Gateshead

United Kingdom

NE9 6SX

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Gateshead Health NHS Foundation Trust (UK)

Funder Name

NHS R&D Support Funding (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?
Results article	results	01/12/2009		Yes	No