

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/09/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 15/08/2012	Condition category Cancer	<input type="checkbox"/> 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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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

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

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 measure

Feasibility and acceptability of applying compression stockings.

Secondary outcome measures

Not provided at time of registration

Overall study start date

29/12/2005

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

Age group

Not Specified

Sex

Female

Target number of participants

20

Key exclusion criteria

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

Date of first enrolment

29/12/2005

Date of final enrolment

01/01/2012

Locations**Countries of recruitment**

England

United Kingdom

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

Sponsor details

The Department of Health, Richmond House, 79 Whitehall

London

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SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

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

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?
Results article	results	01/12/2009		Yes	No