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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/09/2006	**Overall study status** Completed	
Last Edited 15/08/2012	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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
United Kingdom
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