

Groin ultrasound and fine needle aspiration cytology in the conservative management of the groin nodes in primary squamous cell cancer of the vulva

Submission date 30/09/2004	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 30/09/2004	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 20/04/2018	Condition category Cancer	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

N0258123595

Study information

Scientific Title

Groin ultrasound and fine needle aspiration cytology in the conservative management of the groin nodes in primary squamous cell cancer of the vulva

Study objectives

To compare groin and lower limb morbidity in the groin surgery group (GS) and the non-groin surgery group (NGS). Comparison of quality of life between the two groups. Events will be recorded for all patients (such as time to local or regional recurrence).

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)

Treatment

Health condition(s) or problem(s) studied

Cancer: Vulva

Interventions

Randomised, non-blinded (Phase 2): Groin node surgery (GS) versus no groin node surgery (NGS)

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

If this study shows that in patients with squamous cell cancer of the vulva and with a negative groin USS and FNAC groin node surgery can be safely avoided then this will have a major impact in the following areas:

1. Improved quality of life with patient morbidity
2. Increased demand on the radiology services and, in particular, a need for a dedicated radiologist to undertake the initial USS assessment and subsequent USS surveillance. Such skills should be available in a Cancer Centre treating gynaecological cancer patients.
3. Potentially this study could lead to a fundamental change in the management of the groin nodes in vulval cancer
4. Likely reduction in hospitalisation following surgery
5. Likely reduction in the time to return to work and/or return to normal activities

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/12/2006

Eligibility

Key inclusion criteria

Not provided at time of registration

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Female

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/05/2003

Date of final enrolment

31/12/2006

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Royal Marsden NHS Trust

London

United Kingdom

SW3 6JJ

Sponsor information

Organisation

Department of Health

Funder(s)**Funder type**

Government

Funder Name

The Royal Marsden NHS Trust (UK)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration