

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

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 20/04/2018	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

## Study design

Randomised controlled trial

## Primary study design

Interventional

## 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