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# 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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| **Submission date**<br>30/09/2004 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[_] Results<br>[_] Individual participant data<br>[_] Record updated in last year |
| **Registration date**<br>30/09/2004 | **Overall study status**<br>Completed | |
| **Last Edited**<br>20/04/2018 | **Condition category**<br>Cancer | |

**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 pairticular, 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

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |