ISRCTN82982873 https://doi.org/10.1186/ISRCTN82982873

# 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

**Contact name**
Mr Desmond Barton

**Contact details**
Gynaecology Unit
Royal Marsden NHS Trust
Fulham Road
Chelsea
London
United Kingdom
SW3 6JJ
+44 (0)20 7352 8171
desmond.barton@rmh.nhs.uk

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

### ClinicalTrials.gov number

### Secondary identifying numbers
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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

### 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 measure
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

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
01/05/2003

### Completion date
31/12/2006

## Eligibility

### Key inclusion criteria
Not provided at time of registration

### Participant type(s)
Patient

### Age group
Not Specified

### Sex
Female

### Target number of participants
Total number Royal Marsden Hospital (RMH) patients 40

### 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**
England

United Kingdom

**Study participating centre**
**Royal Marsden NHS Trust**
London
United Kingdom
SW3 6JJ

# Sponsor information

**Organisation**
Department of Health

**Sponsor details**
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

**Sponsor type**
Government

**Website**
http://www.dh.gov.uk/Home/fs/en

# Funder(s)

**Funder type**
Government

**Funder Name**
The Royal Marsden NHS Trust (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