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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

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