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GROningen INternational Study on Sentinel nodes in Vulvar cancer. An observational study.

Submission date 19/07/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 19/07/2006	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 12/07/2011	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
http://www.cancerhelp.org.uk/trials/a-study-looking-at-testing-sentinel-lymph-nodes-radiotherapy-and-chemotherapy-for-vulval-cancer

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Acronym
GROINSS-V II

Study objectives
It is safe to omit full inguinofemoral lymphadenectomy in vulvar cancer patients with a negative sentinel node and to replace full inguinofemoral lymphadenectomy by radiotherapy in patients with a positive sentinel node.

Please note that as of 08/02/2012 the anticipated end date for this study has been extended from 31/12/2009 to 31/01/2012.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
An observational study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Vulvar cancer

Interventions
Sentinel node detection, omission of full inguinofemoral lymphadenectomy in vulvar cancer patients with a negative sentinel node and to replace full inguinofemoral lymphadenectomy by radiotherapy in patients with a positive sentinel node

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Groin recurrences

Key secondary outcome(s))
Treatment-associated morbidity

Completion date
31/12/2009

Eligibility

Key inclusion criteria
1. T1, T2 (<4 cm) primary squamous cell carcinoma of the vulva
2. Depth of invasion >1 mm
3. Not encroaching in urethra, vagina or anus with clinically negative inguinofemoral lymph nodes
4. Preoperative imaging does not show enlarged (<1.5 cm) or suspicious nodes
5. Informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Inoperable tumors and tumors with diameter >4 cm
2. Patients with inguinofemoral lymph nodes, at palpation clinically suspect for metastases, at radiology enlarged (>1.5 cm) or suspicious groin nodes and with cytologically proven inguinofemoral lymph node metastases
3. Patients with multifocal tumors

Date of first enrolment
01/12/2005

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Center Groningen
Groningen
Netherlands
9700 RB

Sponsor information

Organisation
University Medical Center Groningen (UMCG) (The Netherlands)

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type
University/education

Funder Name
University Medical Center Groningen (UMCG)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration