

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

Contact name

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Additional identifiers

Study information

Scientific Title

Acronym

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

Primary study design

Observational

Study design

An observational study

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