

GROINSS-V I

GROningen
INternational Study on
Sentinel nodes in Vulvar
cancer

Design

- Multicentre observational study
- Stopping rules for groin recurrences
- Quality control:
Successful experience with the SN
procedure with subsequent
inguinofemoral lymphadenectomy ≥ 10
vulvar cancer patients

Aims

- To investigate the safety and clinical utility of the SN procedure in early stage vulvar cancer patients
- To compare morbidity between SN removal only and inguinofemoral lymphadenectomy

Conclusions

- SN procedure is a safe treatment option in patients with early stage unifocal vulvar cancer
- SN procedure results in decreased morbidity without compromising groin recurrence or survival rates
- Groin recurrences do occur and are often attributable to surgeon and procedure related factors

VOLUME 26 · NUMBER 6 · FEBRUARY 20 2008

JOURNAL OF CLINICAL ONCOLOGY

ORIGINAL REPORT

Sentinel Node Dissection Is Safe in the Treatment of Early-Stage Vulvar Cancer

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GROINSS-V II

A second Observational study !!

GROINSS-V II

(general outline)

For negative SN:

- No full lymphadenectomy
- Stopping rules as in GROINSS-V I

GROINSS-V II

(general outline)

For positive SN:

- No full lymphadenectomy
- Radiotherapy

GROINSS-V II

(rationale)

For negative SN:

Numbers of groin recurrence in GROINSS-V I is so low (preliminary) that a randomized trial is hard to justify

Continuation of monitoring of quality of care !

GROINSS-V II

(rationale)

Results GROINSS-V I for positive SNs:

Additional mets. at full lymphadenectomy, when pos SN detected by:

Routine: 36% (95% CI: 23-51)

Ultrastaging: 8%; (95% CI: 2-21%)

GROINSS-V II

(rationale)

Conclusion GROINSS-V I:

When the SN shows metastatic disease, regardless of size, further treatment of the groin is indicated.

GROINSS-V II

(rationale)

Literature + recent experience:

Treatment-related morbidity of the groin is especially related to full lymphadenectomy plus radiotherapy

Radiotherapy (right dose, right depth, etc.) is able to sterilize microscopic disease in the groin.

GROINSS-V II

(rationale)

Preliminary clinical experience:

Treatment-related morbidity of the groin after SN plus radiotherapy: mild.

GROINSS-V II

Inclusion criteria

- T1/2 tumors, < 4 cm
- Squamous cell carcinomas (SCC)
- Depth of invasion > 1mm
- Clinically no suspicious groin nodes

GROINSS-V II

(protocol)

- Pre therapy: CT/MRI groins
- SN detection: combined technique (preferred)
- No frozen section, pathologic ultrastaging
- Quality control

GROINSS-V II

(protocol)

SN negative:

Close follow-up by experienced clinician
Stopping rules as in GROINSS-V I

GROINSS-V II

(protocol)

SN positive:

- No full lymphadenectomy
- Radiotherapy according to protocol (50 Gy)
- Stopping rules based on a recurrence rate of 4 % with maximum increase of 6 %.
- Patients with pos SN needed: 135

GROINSS-V II

(time frame)

January 2006: Start inclusion

Current accrual rate: 100 pts / year (80 neg SN /
20 pos SN / year)

Dec 2010: End of inclusion.

Dec 2012: Final analysis.

GROINSS-V II

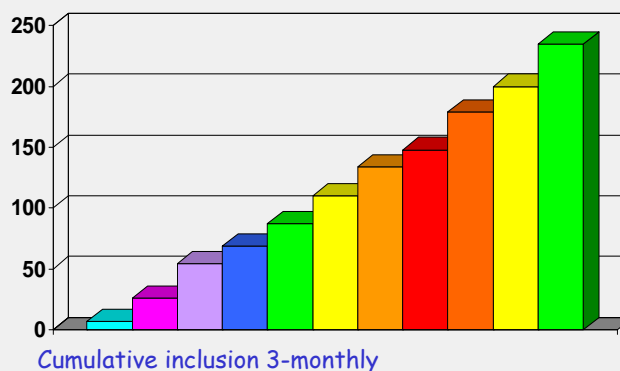
(time frame II)

Accrual can be improved by interested
and experienced centers from:

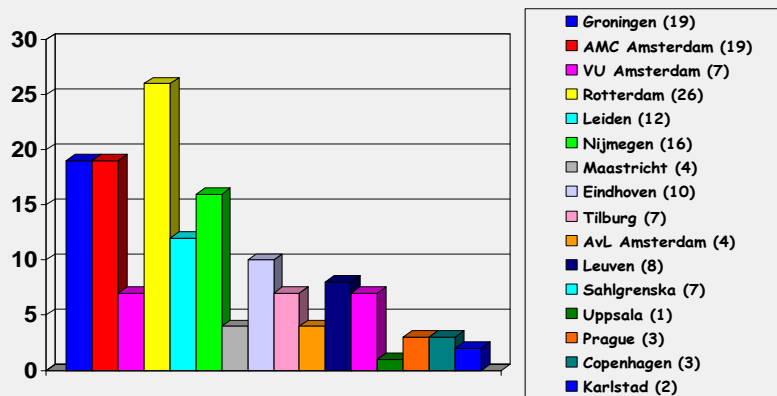
France, Germany, UK, Canada, etc.

Within ENGOT

Accrual since January 2006
until August 2008 (N = 235)



Participating Centers (n = 16)



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