

FAST FACTS

NRG GY024 - GRONINGEN INTERNATIONAL STUDY ON SENTINEL NODES IN VULVAR CANCER (GROINSS-V) III: A PROSPECTIVE PHASE II TREATMENT TRIAL

Eligibility criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

1. Histological confirmed primary SCC of the vulva
2. T1 tumor, not encroaching urethra/vagina/anus
3. Depth of invasion > 1mm
4. Tumor diameter < 4cm
5. Unifocal tumor
6. **No enlarged (>1.5cm) or suspicious inguinofemoral lymph nodes at imaging (CT/MRI/ultrasound)**
7. Possibility to obtain informed consent
8. **Metastatic sentinel lymph node; size of metastasis > 2mm and / or extracapsular extension, or**
9. Metastatic sentinel lymph node: more than 1 SN with metastasis ≤ 2mm
10. **Patients are able to understand requirements of study, provide written informed consent and comply with the study and follow-up procedures**
11. Adequate bone marrow, renal and liver function:
 - a. Absolute neutrophil count ≥ 1.5 x 10⁹ /L
 - b. Platelet count ≥ 100 x 10⁹ /L
 - c. Creatinine clearance ≥ 40 ml/min measured by the Cockcroft Gault formula
 - d. Total bilirubin < 1.25 x ULN
 - e. Aspartate transaminase (AST) and alanine transaminase (ALT) ≤ 2.5 x ULN
12. **Performance status of 0, 1 or 2 on the Eastern Cooperative Oncology Group (ECOG) Scale (Appendix A)**
13. Age 18 years or older
14. Life expectancy of ≥ 12 weeks
15. Written informed consent

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

1. Inoperable tumors and tumors > 4cm
2. Multifocal tumors
3. Tumors with other pathology than squamous cell carcinoma
4. **Patients with enlarged / suspicious lymph nodes which are proven metastatic after fine needle aspiration cytology**
5. No other carcinomas, other than basal cell carcinomas, within last 5 years
6. History of pelvic radiotherapy
7. **History of any infection requiring hospitalization or antibiotics within 2 weeks before**

Enrollment

8. Pregnant female or nursing mother
9. Desire to become pregnant
10. Known brain or spinal cord metastases unless adequately treated (surgery or radiotherapy) with no evidence of progression and neurologically stable off anticonvulsants and steroids
11. Unstable angina, myocardial infarction, cerebrovascular accident, > Class II congestive heart failure according to the New York Heart Association Classification for Congestive Heart Failure (see Appendix B) within 6 months before enrollment