

GROINSS-V II

Trial setting: Multicenter observational study - Is radiotherapy a safe alternative for lymphadenectomy in patients with a positive SN ?

Study Design: International Intergroup trial

Sponsor(s): Dutch Cancer Society, NRG (US)

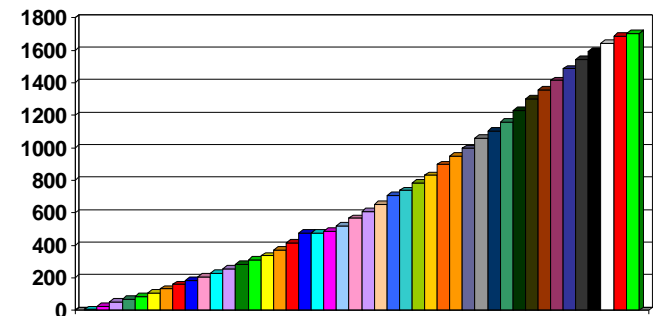
Final No. of patients: 1715 registered patients; completed accrual of 150 patients with micrometastases in the SN

Timeline (first patient – trial closing): Dec 2005 – Oct 2016

Publications: Oonk M et al, Size of sentinel-node metastasis and chances of non-sentinel-node involvement and survival in early stage vulvar cancer: results from GROINSS-V, a multicentre observational study. Lancet Oncol 2010

Analysis: ongoing

Planned publications: Final results early 2019



- Aim: investigate the effectiveness and safety of **chemoradiation in patients with a macrometastasis (>2mm) in the SN**
- Observational study with stopping rules
- Inclusion criteria:
 - Same criteria for SN procedure as in GROINSS-V-II
 - Only patients with positive SN will be included
- SN micrometastasis -> Radiation therapy alone (GROINSS-VII)
- **SN macrometastasis > 2mm -> Concurrent chemoradiation**
 - **48.6 Gy with simultaneous boost to 56 Gy**
 - **Chemo: Cisplatin weekly**
- Ethics Cttee: final approval obtained June 2018.
- Funding application submitted to Dutch Cancer Society – revised version to be submitted December 2018
- Aim to open the study with temporary grant late 2018 / early 2019