

VULVAR CANCER: Phase II study

Inclusion and exclusion criteria

- Primary or recurrent squamous cell cancer of the vulva with locally advanced disease not curable with surgery unless extensive reconstructive;
- Surgery or a colostomy or urostomy is performed;
- Amenable to curative treatment;
- No disease present outside the pelvis;
- Performance status WHO 0-2;
- Patients must be fit enough to undergo salvage surgery after chemo radiotherapy;
- Measurable disease at least locally (vulvar area);
- Pretreatment laboratory values - Hb > 6.5 mmol/l;
- Neutrophil count > $1.5 \times 10^9/l$;
- Platelets $\geq 100 \times 10^9/l$;
- Bilirubin < $25 \mu\text{mol/l}$;
- Adequate liver function: ALAT and ASAT < 2.5 upper normal limit;
- Alkaline phosphatase < 2.5 upper normal limit;
- No upper age limit specified. Patients should mentally, physically and geographically be able to undergo treatment and follow-up;
- Patients must be > 18 years old;
- Written informed consent;
- No psychosis, CNS disease or other expected difficulty for follow-up;
- No active uncontrolled infection;
- No concomitant or previous malignancy other than basal cell carcinoma of the skin or CIN of the cervix