# Prevention of wound complications following inguinal lymph node dissection in patients with penile cancer using epidermal vacuum-assisted wound closure (PräVAC)

## EUDAMED: CIV-12-07-008204

## Synopsis

| Title | Prevention of wound complications following inguinal lymph node dissection in patients with penile cancer using epidermal vacuum-assisted wound closure (PräVAC) |
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| Patient cohort | 100 patients with penile cancer and indication for inguinal lymph node dissection (tumor stage ≥ pT1 G2 or persisting palpable enlarged lymph nodes after antibiotic treatment for 4 to 6 weeks) |
| Rationale | Despite careful surgery and ligation of lymphatic vessels postoperative wound complications like wound dehiscence, lymphocele formation, persisting lymphorrhea or lymph edema occur in 30 – 70 % of patients following inguinal lymph node dissection requiring further treatment in up to 30% because of pain, infection or compression of blood vessels (EAU Guidelines 2009). Apart from these complications and diminished quality-of-life also deferral of further oncological treatment may result leading to worse prognosis in these patients. Currently only a limited body of evidence exists concerning prevention of these adverse effects after inguinal lymph node dissection. Elaborate surgical modifications like inguinal placement of an omentum flap, applying matrix gel or systemic octreotide have been proposed. Although vacuum-therapy has been described in case reports for the treatment of inguinal lymphorrhea, up to now no trial investigating preventive epidermal vacuum-assisted wound closure after inguinal lymph node dissection has been undertaken. It is proposed that subatmospheric pressure causes compression and facilitated closure of lymphatic vessels as well as constant removal of wound exsudate and thus prevention of lymphocele formation. Furthermore epidermal vacuum-assisted therapy is expected to support wound closure. A positive influence on |
Postoperative wound healing could be observed in several initial studies including own observations concerning epidermal vacuum-assisted wound closure. In case epidermal vacuum-assisted therapy proves beneficial for the prevention of postoperative wound complications after inguinal lymph node dissection, it may be able to lower the rate of further complications as well as the duration of hospitalization and may improve quality-of-life and even oncological outcomes in those patients.

**Trial design**

Multicenter nationwide (Germany) interventional clinical trial; postoperatively after bilateral inguinal lymph node dissection, placement of a subcutaneous suction drainage and wound closure using staples or single-knot sutures patients receive conventional compression bandages for 24 hours (standard treatment) on one side and epidermal negative-pressure wound dressings for 7 – 8 days (intervention) on the other side. Localization of the epidermal negative-pressure wound dressing is determined according to randomization. Further postoperative treatment corresponds to clinical routine (2 days of immobilization; indwelling subcutaneous drainages for at least 4 days and removal only after cessation of exudation).

**Aim of study**

Primary endpoint:
cumulative drained exudate volume (ml) until removal of drainage (up to the 14th postoperative day)

**Secondary endpoints:**

A) maximal drained exudate volume per day (ml)

B) duration of indwelling drainage (time until removal)

C) incidence of wound-associated complications (lymph edema, lymphocele, lymphorrhrea, wound dehiscence, wound infection, thrombosis)

D) duration of hospitalization

E) comparison of lymph node dissection-associated rate of reintervention (recurrent placement of drainage, puncture, re-operation, irradiation therapy, other therapeutic interventions)

F) quality-of-life, patient`s satisfaction and comfort with wound treatment

**Timeline**

Recruiting until 31st of December 2016.

**Inclusion criteria**

- Patients with penile cancer and indication for inguinal lymph node dissection (tumor stage \( \geq \text{pT1 G2} \) or palpable inguinal enlarged lymph nodes)
- Self-signed and –dated informed consent

**Exclusion criteria**

- Previous inguinal surgery (e.g. after femoral bypass surgery) or other medical conditions already impairing lymphatic drainage (status postinguinal hernioplasty does not represent an exclusion criteria in case surgery hasn`t been performed within the last 3 months and no apparent impaired lymphatic drainage is present)
- Patients unable to understand the patient information or unable to consent
- Patients with known allergy to acrylic adhesive
- Age below 18 years