Closed Incision Wound Therapy (PICO) On Wound Healing and Scar Quality

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21787

Source
NTR

Brief title
PICO-trial

Health condition

Wondgenezing, post-operatieve complicaties en pathologische littekenvorming.

Wound healing, post-operative complications and pathological scar formation.

Sponsors and support

Primary sponsor: AUMC, locatie VUmc
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

The primary parameters will concern wound healing complications (infection, seroma, hematoma, dehiscence, reoperation).

Secondary outcome

The secondary parameters will concern the outcomes of scar quality (POSAS, Cutometer®, SCAR-Q and DSM-II colormetric evaluation). Additional endpoints will be revision surgery, CHEST-Q scores, nipple survival and nipple sensitivity.

Study description

Study objective

The treatment with ciNPT results in a superior healing when compared to the standard treatment (no ciNPT). The rationale behind the secondary outcome is that this treatment leads to improvement of scar quality in comparison to the standard treatment (no ciNPT).

Study design

The primary endpoint is at 1 month post-op, whereas the secondary endpoint is at 1 one year post-op

Intervention

The bilateral mastectomy sites will be closed conventionally and in accordance to standard practice. All mastectomies will be randomly assigned one control side and one case side that will receive the additional ciNPT treatment.

Contacts

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Eligibility criteria

Inclusion criteria

• Only patients that meet the age criterion of >18 years old will be considered for participation.

• Written informed consent by the patient and/or legal representative

• Trans men that request a bilateral mastectomy as a masculinization procedure.

Exclusion criteria

• Patients with known underlying or concomitant medical conditions that may interfere with normal wound healing (e.g. systemic skin and connective tissue diseases, any kind of congenital defect of metabolism including insulin-dependent diabetes mellitus, Cushing syndrome or disease, scurvy, chronic hypothyroidism, congenital or acquired immunosuppressive condition, chronic renal failure, or chronic hepatic dysfunction (Child-Pugh class B or C), severe malnutrition, or other concomitant illness which, in the opinion of the Investigator, has the potential to significantly delay wound healing)

• Severe drug, smoking (> 1 pack a day; 22 cigarettes) and alcohol abuse (>10 alcoholic units a week)

• Patients expected not to comply with the study protocol (including patients with severe cognitive dysfunction/impairment and severe psychiatric disorders)

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-08-2018
Enrollment:	85
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-07-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7213
NTR-old	NTR7412
Other	NL64838.029.18 : 2018.145

Study results