A comparison between high and low pressure continuous closed suction drainage systems - A prospective intra-individual randomized controlled study of drainage management after chest wall masculinization in female-to-male transgenders

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Aim of the study is to compare the efficacy and safety of the use of a low vacuum constant drainage system (Palin®) with a high vacuum closed suction drainage system (Medinorm S-400®) after chest wall masculinization in female-to-male transgenders.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Breast therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON40288

Source
ToetsingOnline

Brief title
High versus low pressure suction wound drainage after breast surgery

Condition

- Breast therapeutic procedures

Synonym
wound treatment after breast surgery

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,CayMedic BV

Intervention

Keyword: Breast surgery, Closed suction drainage system, Drainage, Transgender

Outcome measures

Primary outcome

The primary outcome of the study is drain production over time (first peak, (3h post-operative), first 24h post-operative and total production), up to the point of removal of the drainage system.

Secondary outcome

- edema and fluid collection in surgical space (measured by ultrasound diagnostics);
- device related adverse events (eg. blockage of drains);
- daily pain and pain upon removal of the drains;
- complications;
- wound closure, and aesthetic result.
- cost-effectiveness;
- surgeon*s & (operating room) nurse*s preferences

Study description

Background summary

Breast surgery is a major domain of plastic surgery practice and comprises procedures of amputation, reduction, augmentation and reconstruction. Main complications of breast surgery include development of hematoma or seroma, infection and wound healing problems. Other technique-specific complications are nipple-areola necrosis (breast reduction), implant rupture & capsular contraction (reconstruction or augmentation), or flap failure (Stojkovic et al., 2013).

Drain insertion is usually the final step of surgical breast procedures, and serves a multi-purpose role; (1) preventing fluid collection, (2) eliminating the dead space, and (3) approximating tissue to foster adequate wound healing. Surgical drains can be subdivided into open and closed (or intermittent vs. continuous) systems, with passive or active suction. Other characteristics include the strength of negative pressure applied and aspect of drain tubes (Stojkovic et al., 2013).

Although surgical drain use is associated with the previously mentioned clinical advantages, conflicting findings have been published on the type of drains to be used preferentially. Reported drain related complications include persisting hematoma and fluid production, and drain-specific complications (Stojkovic et al., 2013; Kosins et al., 2013). Some of these complications are thought to be the result of the strength of negative pressure applied. Given this ambiguous evidence of clinical effectiveness and burden of post-operative complications, prospective studies of optimal drain use are inevitable. In this study we will specifically compare the efficacy of a continuous low pressure drain system with a high pressure drain system.

Study objective

Aim of the study is to compare the efficacy and safety of the use of a low vacuum constant drainage system (Palin®) with a high vacuum closed suction drainage system (Medinorm S-400®) after chest wall masculinization in female-to-male transgenders.

Study design

The study is a prospective, single blinded, intra-patient randomized controlled study, which will be performed in a single center setting (Jan van Goyen clinic, Amsterdam). The enrolment period is 9 months to 1 year and the follow-up period is maximally 4-8 weeks. Patient*s time commitment for the study is maximally 14 weeks (including pre-operative assessment).

Intervention

All study subjects will receive the most suitable surgical technique of chest wall masculinization based on breast tissue volume and ptosis, and skin

elasticity and surplus (Cregten-Escobar et al., 2012; Monstrey et al., 2008).
At the end of the surgery the specialist will leave one high and one low vacuum continuous closed suction drainage system in situ according to pre-operative randomization:

group 1: high pressure system left hemithorax & low pressure system right hemithorax
group 2: low pressure system left hemithorax & high pressure system right hemithorax

The drain tube, type fluted (Palin®) or middle perforated (Medinorm S-400®), will be inserted in the surgical space my means of the trocar. The drain tube will be inserted halfway of the predefined range, as advised by the manufacturers and will be attached to the patients skin by means of non-absorbable sutures.

Drains will be left in the wound based on fluid production and will be removed either before discharge (in case of low/moderate postoperative production) or after discharge (in case of high postoperative production). When drain production drops after discharge, patients will contact the investigator to plan drain removal at the outpatient clinic of VU university medical center.

Study burden and risks

Recruited patients will be treated according to normal standards of care. There is no direct benefit of the study to the patients included in the study. However, the study will objectively assess the results and complications of two drain systems and thus provide evidence to assess whether there are differences between these options. This information will benefit future patients who will undergo these procedures. The extra burden for the patient includes the completion ultrasound and extra questions on pain, satisfaction and functioning during outpatient clinic visits. The risks involved are expected to be equivalent to the risk of the standard procedures.

- asymmetry of post-operative results: impact: low, likelihood: low;
- moderate complications (e.g. infection, small haematoma): impact: moderate, likelihood: no added risk;
- severe complications (e.g. 2nd surgery, major abscess): impact: severe, likelihood: no added risk.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- aged 18 or older;
- qualify for bilateral mastectomy in the context of FtM sex reassignment;
- indication for post-operative drainage use;
- ability to give informed consent,
- willing to participate.

Exclusion criteria

- shows evidence of alcohol and/or drug abuse;
- has a local or general infection which could jeopardize the surgical objective;
- has proven or suspected hypersensitivity to materials;
- has immunosuppressive pathologies.
- has (a history of) breast cancer;
- has ongoing severe psychiatric illness or mental retardation or is unable to communicate adequately

Study design

Design

Study type: Interventional

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-09-2014
Enrollment:	35
Type:	Actual

Medical products/devices used

Generic name:	Wound drainage system
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	23-05-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL47275.029.13

Study results

Date completed: 31-10-2015

Actual enrolment: 3

Summary results
Trial ended prematurely