An Observational, Prospective Multicentre Clinical Study to assess the safety and clinical performance of a New Single-use Negative Pressure Wound Therapy System (PICO 7Y) for the Simultaneous Management of Bilateral Closed Incisions in Oncoplastic Breast Surgery Patients

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The aim of this study is to assess the safety and clinical performance (both for patient and doctors) of the PICO 7Y system in delivering NPWT simultaneously to two closed incisions following bilateral oncoplastic breast surgery.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Breast therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON48115

Source
ToetsingOnline

Brief title
PICO7Y

Condition

- Breast therapeutic procedures

Synonym
breast cancer surgery, Oncoplastic breast surgery

Research involving
Human

Sponsors and support

Primary sponsor: Smith&Nephew, Inc
Source(s) of monetary or material Support: Door de opdrachtgever Smith&Nephew

Intervention

Keyword: Negative pressure wound therapy, Oncoplastic breast surgery, PICO7Y

Outcome measures

Primary outcome

To assess clinical performance and safety of the PICO 7Y NPWT system through its capacity to deliver negative pressure consistently at -80 mmHg, to both the reconstructed breast and the contralateral breast, during a period of 7 days including the rate of leakage.

Secondary outcome

To assess the clinical performance and safety of the PICO 7Y NPWT system within 30 days of surgery, the following evidence is taken into account:

* The rate of successful wound healing at 14 and 30 days of surgery. The wound healing is successful if there are no signs of surgical site complications (SSC) such as persistent exudate, dehiscence, necrosis, seroma, hematoma or infection.
* The incidence of SSC including infection, dehiscence or delayed wound healing at day 14 and day 30. Please note delayed wound healing is healing that takes

longer than 10 days.

* The visual appearance rating of quality of wound closure. Healing rates will be considered overall and separately for the oncologic side and the contralateral side (this is because the risks are different).

* The pain experienced by the subject during the use of the PICO 7Y NPWT system.

* The dressing wear time (time in days) and the number of dressings used per surgical site.

* To evaluate change in health related quality of life, associated with treatment, measured using change of the EQ-5D 5L scores from baseline to Day 7 and Day 30.

Exploratory

* To assess clinician acceptability of PICO 7Y dressing at 7 days, and clinician satisfaction with the outcome at 30 days.

* To assess patient acceptability of PICO 7Y dressing at 7 days.

* To assess ease of application & removal of the PICO 7Y dressing.

* To assess patient comfort during wear.

Safety

* Analysis of adverse events experienced by subjects over a 30-day follow-up period.

* Device-related adverse events and device deficiencies (quality issues) during

the period subjects receive NPWT therapy with PICO 7Y.

Study description

Background summary

Negative pressure wound therapy (NPWT) becomes more popular as a post-operative dressing for closed surgical incisions. In current literature NPWT use on general surgical closed incisions has been reported to reduce surgical site complications including infection, dehiscence and delayed healing. The PICO pump is canister-free, disposable and a single use NPWT device which generates an effective nominal negative pressure of -80 mmHg and provides therapy during seven days after surgery. Although some evidence exists which supports the positive effects of NPWT in oncoplastic breast surgery closed incisions wounds, there is no evidence in relation to single-use systems treating both wounds simultaneously. PICO 7Y is a new variant of the already existing PICO system. It has the ability to deliver negative pressure simultaneously across two wound beds or closed incisions and their surrounding area instead of just one wound. Previous studies have focused on NPWT systems with the ability to only supply negative pressure to a single wound. The technical applications of the systems are comparable, but the application of this Y-connection system may represent a possible cost saving solution to the current PICO system in bilateral wounds.

Study objective

The aim of this study is to assess the safety and clinical performance (both for patient and doctors) of the PICO 7Y system in delivering NPWT simultaneously to two closed incisions following bilateral oncoplastic breast surgery.

Study design

The study will comprise a prospective, open-labelled, multicenter study to evaluate the use of the PICO 7Y system in closed incision NPWT during oncoplastic breast surgery and contralateral reconstruction. Individual participation in the study will last for 30 days (7 days treatment with the PICO 7Y system with follow-up until day 30). The standard measurements (questionnaire and pictures) will take place pre-operatively and at day 7, 14 end 30 post-operatively in the same hospital and will be performed by the same doctors or nurses.

Study burden and risks

The risks to which the participants are exposed are neglectable for this

research. All dressings that are used for treatment of the patient are already available on the market and have been used before for the treatment of patients with similar unilateral operation wounds (PICO).

Potential advantages:
- Previous research with a precursor of the PICO-7Y system for breast reductions has shown that fewer wound complications have occurred in the first three post-operative weeks compared to a breast treated with only normal dressings and without the PICO-system.
- The cosmetic aspect of the scar has shown better results in the first six months after surgery with the PICO7Y system. However, this difference disappeared after one year.
- This research will result in valuable information for the producer concerning the efficiency, safety and patient satisfaction of the PICO7Y.

Potential disadvantages:
- The patient has to carry the pump that is connected to the dressings with her all the time during the first 7 days after surgery. However, the pump is very small and light weight and therefore it does not affect the mobilization of the patient.
- Negative wound pressure could be experienced as uncomfortable. However previous research showed a very high patient satisfaction for this aspect of the wound system.
- The patient is obliged to additionally visit the clinic for two more times. Moreover, the extra time needed filling out the questionnaires has to be considered.
- In rare situations the patient might be hypersensitive or allergic to the dressing which can cause redness, pain, a burning or itchy feeling, blistering or peeling off the skin. If so, the dressings will be removed and the doctors will decide on an alternative dressing or treatment.
- The PICO7Y pump contains a magnet. This implies the pump must be kept away from any other medical devices such as pacemakers, defibrillators, neurostimulators, cochlear implants, insulin pumps or other life supporting equipment for at least 10cm.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. The subject must have understood and provided written informed consent
2. Female subjects who must be at least eighteen (18) years of age.
3. Willing and able to make all required study visits.
4. Able to follow instructions.
5. Subjects must be undergoing, at the same time, both an oncoplastic breast surgery and a symmetrising breast reduction on the contralateral breast and have closed incisions that would benefit from NPWT.
6. Subjects whose incisions will fit comfortably within the area of the pad of the dressing sizes provided.

Exclusion criteria

1. Contraindications (per the PICO 7Y IFU) or hypersensitivity to the use of the investigational product or their components (i.e., silicone adhesives and polyurethane films [direct contact with wound], acrylic adhesives [direct contact with skin], polyethylene fabrics and super-absorbent powders [polyacrylates]) within the dressing.
2. Subjects with skin features (e.g. tattoos, skin colour, pre-existing scarring) which in the opinion of the Investigator, will interfere with the study assessments.
3. Suspected or confirmed allergy to any of the components of the ancillary

products should they be deemed required, e.g. in the case of SECURA No-sting barrier skin wipes for patients with fragile skin.
4. Subjects with a local infection, close or at the site of the incision, at the time of surgery
5. Subjects with incisions that are actively bleeding unless haemostasis has been achieved.
6. Subjects with a genetic or acquired disease capable of negatively impact the closed incision healing.
7. Subjects with a history of poor compliance with medical treatment.
8. Subjects who have participated previously in this clinical trial.
9. Subjects with a medical or physical condition that, in the opinion of the Investigator, would preclude safe subject participation in the study.
10. Individuals from vulnerable populations including pregnant women and adult females over 75 years.
11. Subjects who have received neo adjuvant chemotherapy within the last 30 days prior to surgery.
12. Patients who at the end of the surgery have only one breast operated.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-12-2019
Enrollment:	6
Type:	Actual

Medical products/devices used

Generic name:	PICO7Y
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	09-10-2019
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL71191.096.19