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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21787

Bron
Nationaal Trial Register

Verkorte titel
PICO-trial

Aandoening

Wondgenezing, post-operatieve complicaties en pathologische littekenvorming.

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

Ondersteuning

Primaire sponsor: AUMC, locatie VUmc
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Doel van het onderzoek

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).

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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)

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-08-2018
Aantal proefpersonen:	85
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	30-07-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten