Injection of Autologous Stromal Vascular Fraction enriched lipoaspirate for the treatment of vulvar Lichen Sclerosus

Gepubliceerd: 21-07-2019 Laatst bijgewerkt: 15-05-2024

Expected reduction of 25% on the DQOL score.

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

Samenvatting

ID

NL-OMON23776

Bron
NTR

Verkorte titel
TBA

Aandoening

Vulvar Lichen Sclerosus

Ondersteuning

Primaire sponsor: None
Overige ondersteuning: UMCG

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Efficacy is determined by the quantification of improvement in patient’s symptoms by improvement in quality-of-life and sexual functioning three months, six months and one year

after injection of SVF enriched lipoaspirate. Quality of life is evaluated using the validated Dermatology Life Quality Index (DLQI) and resumption of sexual activity and quality of sexual functioning is evaluated using the validated Female Sexual Function Index (FSFI).

Toelichting onderzoek

Achtergrond van het onderzoek

Lichen sclerosis (LS) is a chronic inflammatory dermatosis with a high prevalence in the genital area in peri- or postmenopausal women. Vulvar LS presents with progressive pruritus and pain, sexual and urinary dysfunction, reduced quality of life, and an increased risk of vulvar squamous cell carcinoma. In patients treated for vulvar cancer, the presence of LS appears to affect the incidence of recurrence of squamous cell carcinoma.
Transfer of adipose tissue, also known as lipofilling, is recognized as a promising and novel technique for the treatment of a range of pathologies. The white adipose tissue harbors a mesenchymal cell population with stem cell-like properties, which holds regenerative potential.
The aim of the study is to evaluate the safety and efficacy of lipofilling with additional SVF-enriched lipoaspirate for the treatment of vulvar LS in non-responders to conventional treatment. Efficacy is determined by the quantification of improvement in patient's symptoms by improvement in quality-of-life and, if applicable, in sexual functioning. Secondary objectives are the quantification of improvement in clinical signs by physical examination findings and improvement of histopathological parameters. In addition the molecular mechanism of regeneration of sclerosis is evaluated

Doel van het onderzoek

Expected reduction of 25% on the DQOL score.

Onderzoeksopzet

3,6 and 12 months

Onderzoeksproduct en/of interventie

Pilot study to evaluate the safety and efficacy of vulvar injection of SVF enriched lipoaspirate in women with therapy-resistant vulvar LS.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Postmenopausal women up to 80 years with ASA Physical Status Classification 0-1
• Histopathological confirmed diagnosis of lichen sclerosus
• Moderate or severe LS (IGA scale 3 or 4), therapy resistant to conventional therapy with highly potent topical steroids
(insufficient reduction in clinical symptoms and signs having used topical steroids for 6 months).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Women with history of vulvar cancer or VIN in addition to lichen sclerosus.
• An oncological event in the patient’s history < 5 years ago.
• A known systemic disease that will impair wound healing (e.g. diabetes mellitus type I, known atherosclerosis with an event
that required hospitalization, collagen diseases, diseases of the skin, HIV).
• Systematic use of prednisone or other immunotherapy.
• Use of anticoagulant therapy.
• Smoking.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	21-07-2019
Aantal proefpersonen:	15
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	21-07-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48736
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7908
CCMO	NL65403.000.18
OMON	NL-OMON48736

Resultaten