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

No registrations found.

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

Summary

ID

NL-OMON23776

Source
NTR

Brief title
TBA

Health condition

Vulvar Lichen Sclerosus

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: UMCG

Intervention

Outcome measures

Primary outcome

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).

Secondary outcome

The quantification of improvements in clinical signs and architectural changes by physical examination findings and improvements of histopathological parameters

Study description

Background summary

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

Study objective

Expected reduction of 25% on the DQOL score.

Study design

3,6 and 12 months

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

• 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).

Exclusion criteria

• 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.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-07-2019
Enrollment:	15
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	21-07-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48736
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results