Tacrolimus as Treatment of Breast Cancer-Related Lymphedema

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Background and Aim: Breast cancer-related lymphedema is a severe and life-long side-effect to breast cancer treatment. The condition increases the risk of infections and decreases health-related quality of life (HR-QOL) in patients. No prophylactic or curative treatment is currently available for this condition.
CD4+-cells plays a critical role in the development of lymphedema. The cells facilitate inflammation and fibrosis formation in the subcutaneous tissue, which inhibits lymphatic regeneration. Tacrolimus is an immunosuppressive and anti-inflammatory macrolide that targets the CD4+-cells. Tacrolimus as treatment of lymphedema has already shown promising results in animal studies. Tacrolimus has the potential to cure an otherwise uncurable and life-long side-effect of BC and will therefore benefit a large number of patients who suffers from BCRL.
The aim of this study is to assess the effect of Tacrolimus treatment on breast cancer-related lymphedema.

Material and Method: The A pilot study with a planned inclusion of 20 patients with a 12-month follow-up period. The purpose of this study is to assess the effect of tacrolimus treatment on lymphedema and HR-QOL. Results are attained from objective measures and questionnaires.
The patients will be seen at a consultation prior to the treatment start and then 3 times hereafter (at 3, 6 and 12 months) as follow up consultations where effect of treatment. The patients will be treated for six months a before the last follow-up consultation.

Primary endpoint:

- Arm volume measured with water displacement test

Secondary endpoints:

- Patient-reported outcome measured through the Danish versions of LYMPH-ICF, DASH and SF-36 questionnaires
- Bioimpedance
- Lymphangiography
- Arm volume measured with measuring tape

Clinical impact: This will be the first clinical pharmacological study on regarding treatment of lymphedema with Tacrolimus. This study will test the feasibility and efficacy of Tacrolimus ointment in a population of breast cancer patients who have developed lymphedema. The

study may lead to a routine clinical implementation of tacrolimus ointment to patients diagnosed with Lymphedema. Regardless of the outcome, the study will benefit the patients and future research in the field of lymphedema.

Results:

Discussion/Conclusion: