



AUTOIMMUNE CONNECTIVE TISSUE DISEASES

## EFFECTS OF POLYDEOXYRIBONUCLEOTIDE IN THE TREATMENT OF SCLERODERMA

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Introduction: Morphea, also known as localized scleroderma, is a chronic autoimmune disorder characterized by skin thickening with an increased deposition of collagen in the lesional site.

Different therapeutic approaches are proposed, but most of them are poorly effective.

Polydeoxyribonucleotide (PDRN) is a drug used for healing of cutaneous wounds. It is known to selectively act on the A2 purinergic receptor to help cell growth and it seems to interfere with several patho-physiological pathways involved in the fibrotic and atrophic skin.

Objective: Aim of this study is to evaluate the efficacy and safety of PDRN in patients with fibrotic and atrophic cutaneous lesions in scleroderma disease.

Materials and Methods: This study is a single center open-label clinical trial with 45 subjects expected. So far 25 patients were enrolled at Policlinico Hospital of Milan. PDRN is administered intramuscularly for 3 months, followed by 3 months of follow up. Primary endpoint for determining efficacy and safety is the clinical improvement determined through LOSCAT Score.

Secondary endpoints are changes in tele-thermographic and ultrasound profile of a selected target cutaneous lesion after PDRN treatment. Moreover, measurement of histology improvement of lesional site after drug administration (especially new vessels formation) and evaluation of patient's satisfaction, through a self-administered Dermatology Life Quality Index, are considered.

The exploratory endpoint is the change in degree of induration of subcutaneous tissue at the level of scleroderma lesion through a new device called SkinFibrometer.

All variables will be summarized using appropriate descriptive statistics.

Results: PDRN therapy was found to significantly modify the degree of induration at the scleroderma lesions and to improve the patient's quality of life. No side effects were found.





Conclusions: Our trial, although preliminary, suggest that PDRN can improve the clinical outcome of patients affected by localized scleroderma, with a good safety profile.

