Clinical Evaluation of induced pluripotent stem cells (iPSc) to cure patients with Psoriasis Vulgaris. An Open Study.

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Rationale: Psoriasis is characterized by prominent hyperplasia of the epidermis because of distinct hyper-proliferation of basal layer keratinocyte progenitors and its critical dependence on T-cell activation. Published clinical data have evidenced that therapies specifically directed at interfering signals delivered to T cell from activating antigen presenting cells, as well as transforming immunoregulatory cytokines and chemokines, such as IL-10, TNF, IL-8, and IL-12 have resulted promising in treating psoriasis.

Objective: To ascertain the clinical efficacy, tolerability and safety of (patient-syngenic) iPSc directed to interfere T-cell activation as well as to modulate immunoregulatory cytokines and chemokines (IL-10, TNF, IL-8 and IL-12) to cure patients affected with psoriasis vulgaris.

Methods: Preselected subjects n=20 (11M/9F), age ranging between 22 and 70 years with slight to moderate chronic plaque-type psoriasis and PASI (Psoriasis Area and Severity Index) scores between 4.8 and 16.7 (mean 9.2) were enrolled for the study. The mean duration of the disease prior to enrollment was 8.7 years (range 1-21). Each patient was allocated a precoded disposable vial/syringe containing syngenic iPS in a vehicle 0.5 ml. Each allocated vial was administered intravenously to the patient by the principal investigator. Patients were examined on a weekly basis and those showing a progressive reduction of lesions, desquamation followed by decreased erythema, infiltration and lower PASI score were considered cured. To monitor post-treatment experience, subjects were given a log to record their daily experience. Photographic and optical techniques were also used both at the baseline and on schedules visits.

Results: There were no dropouts and the treatment was well tolerated by all the patients. Patients did not experience or reported any allogenic rejection or treatment-related adverse event. By the end of six weeks followed up all the patients reported marked clinical beneficial improvement resulting decreased PASI score 1.5. Study was monitored and followed-up for 2 years after the baseline and results showed no recurrence. Patients were very pleased with the exceptionally beneficial results and allowing them to lead stress-free lifestyle.

Conclusion: The study states that induced pluripotent stem cell in a proprietary vehicle administered intravenously is safe, tolerable and significantly beneficial in contributing superior clinical efficacy to cure patients with psoriasis vulgaris. Additional clinical studies are recommended.