570 Assessment of Safety of Autologous Regulatory T-cells in the Treatment of Systemic Sclerosis



RATIONALE: Regulatory T cells (Tregs) represent about 5-10% of the peripheral CD4⁺ T cells, playing a key role in maintenance of immune homeostasis and immunological self-tolerance. Tregs may be used in the treatment of autoimmune diseases. The safety of autologous Tregs infusion for the treatment of systemic sclerosis (SS) (NCT05214014) was assessed. METHODS: 13 patients with SS were studied. Peripheral blood mononuclear cells (PBMCs) obtained from human whole blood by density gradient centrifugation were cultured in RPMI medium for 7-10 days with 20 ng/ml IL-2, 50 ng/ml anti-CD3, 200 ng/ml anti-CD28 which were added every 2-3 days for Tregs differentiation. Tregs were identified as CD45⁺CD4⁺CD25⁺CD127^{low}FoxP3⁺Helios⁺ cells. Autologous Tregs 0.5x10⁶ per kg body weight were injected intravenously over 60 minutes. **RESULTS:** Increased or decreased blood pressure, body temperature, or heart rate were absent in 11 patients; 1 patient had a fever and 2 patients had local inflammation of a trophic ulcer of the hand 1 day after therapy. Allergic reactions were not seen. On blood and urine assessment there were no significant changes indicative of hepato-, nephro- or hemato- toxic effects of Tregs infusion.

CONCLUSIONS: Infusion of Tregs in the treatment of SS was safe and well tolerated. Allergic reactions and serious systemic adverse reactions were not seen.



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