

An Open-Label Phase I Clinical Study: Safety, Tolerability and Pharmacodynamics of Mutant Collagenase Injection in Adults for Localized Fat Reduction

Authors : Yong Cang

Abstract : RJV001 is a subcutaneous injection containing mutated recombinant Collagenase H (ColH), leading to disruption of collagen matrix in adipose tissue and programmed cell death of adipocytes. Here we reported our clinical investigation of the safety, tolerance and pharmacodynamics of localized RJV001 injection into healthy human abdominal fat tissues (NCT04821648, Arizona Research Center). Investigate the safety, tolerance and clinical pharmacodynamics of subcutaneous RJV001 in humans. In the dose-escalating study, 18 subjects completed the study, 100% female, 78% white, with a mean age of 42[±9.9]. All three tested dose (0.05, 0.075 and 0.15 mg/injection), up to 30 injections, were safe and well-tolerated. Bruising and tenderness to palpation, mild to moderate, were the most frequent local skin reactions but nearly all resolved within 30 days. Additionally, physician-monitored ultrasound measurement showed that a reduction in abdominal fat tissue thickness was consistently observed in Cohort C (0.075, 0.15 mg/injection, 30injections), with a mean reduction of 7.37 [± 2.020] mm. Based on this clinical study, RJV001 has been advanced to phase II clinical studies. In the dose-escalating study, subcutaneously administered RJV001 was safe and well-tolerated in healthy adults up to 0.15 mg/injection, 30 injections. Fat reduction and adipocytolysis were observed by ultrasound measurements and histological analysis for exploratory purposes.

Keywords : fat reduction, mutant collagenase, clinical trial, subcutaneous injection

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