A Clinical Study to Assess Histological Changes From Treatment of Poly L-lactic Acid Biostimulator on Women at Various Menopausal Stages

NCT07342400

Status	RECRUITING
Phase	Not Applicable
Sponsor	Galderma R&D
Enrollment	40 participants

Key Eligibility Criteria

Inclusion (6)

- Subjects diagnosed with symmetrical, moderate-to-severe cheek wrinkles on each side of the face as assessed via the Galderma Cheek Wrinkles Scale.
- Subject with intent to undergo correction of cheek augmentation or contour deficiencies
- Subjects willing to have a 3-mm punch biopsy on each preauricular side
- Subjects willing to maintain the current lifestyle, daily routine (e.g., diet, exercise, sleep, etc.), and a stable Body Mass Index (BMI, ± 5 kg/m2) throughout the study
- Ability of giving consent for participation in the study.

... and 1 more (see full listing online)

Exclusion (5)

- Subjects with asymmetrical severity or unidentical cheek wrinkle score between 2 sides of the cheek.
- Subjects with a history of allergy or hypersensitivity to any ingredient of the treatment products.
- Previous tissue-augmenting therapy, contouring, or revitalization treatment in the face, except lips.
- Previous treatment/procedure in the face in the previous 6 months that, in the Investigator's opinion, would interfere with the study injections and/or study assessments or exposed the study subject to undue risk by study participation, or planning to undergo any of these procedures affecting the treatment area at any time during the study.
- Subjects with any medical condition that, in the opinion of the Investigator, would make the subject unsuitable for inclusion.

Locations (2 total)

Miami Dermatology & Laser Institute, Miami, Florida, United States
Day Dermatology & Aesthetics, New York, New York, United States