Evaluation of Performance and Safety of INNEA and INNEA AQUA for the Treatment of Cheek and décolletage Wrinkles

NCT07331181

Status	RECRUITING
Phase	Not Applicable
Sponsor	Innate srl
Enrollment	55 participants

Key Eligibility Criteria

Inclusion (8)

- Patient Informed consent form (ICF) signed;
- Female Subjects between 35 and 65 years old at the time of the signature of ICF;
- Subjects with at least 2 (shallow wrinkles) on the Lemperle Rating Scale requiring correction of cheek wrinkles and/or subjects requiring correction of décolletage wrinkles;
- Willingness to follow all study procedures, including attending all site visits, tests and examinations;
- Agreeing to present at each study visit without make-up;

... and 3 more (see full listing online)

Exclusion (1)

- Other - different - clinical conditions of the skin (i.e. rosacea,psoriasis, vitiligo, active eczema, severe scleroderma, severe acne and diagnosticated cancer with/without ongoing antitumor therapy); 2. Infectious or inflammatory processes near the area of intervention; 3. Presence of naevi in the area to be injected; 4. Ongoing use or exposure to benzalkonium chloride solutions; 5. Patients who tend to develop hypertrophic scarring; 6. Patients with a history of autoimmune disease or who are receiving immune therapy; 7. Patients who are known to be hypersensitive to hyaluronic acid; 8. Presence of cutaneous disease on the tested area, as lesions, malformations and recurrent facial/labial herpes; 9. Presence of tendon, bone or muscular implants near the areaof intervention; 10. Ongoing cutaneous allergies; 11. Known hypersensitivity to cheloids; 12. Allergy or contraindications to device components; 13. Allergy or contraindication to one of the components of local anesthetic (patch or cream); 14. Immune system illnesses; 15. Diabetes mellitus or uncontrolled systemic diseases (endocrine, hepatic renal, cardiac, pulmonary, neurological disorder); 16. Problems with coagulation or undergoing anticoagulant therapy; 17. Patients who are using substances that can prolong bleeding(such as aspirin, nonsteroidal anti-inflammatory drugs, and warfarin); 18. Current treatment with anti-inflammatory drugs, anti-histaminic, topic and systemic corticosteroids, narcotic, antidepressant, immunosuppressive drugs (with the except of contraceptive or hormonal treatment starting more than 1 year ago), drugs able to influence the test results in the investigator opinion; 19. Known drug and/or alcohol abuse; 20. Mental incapacity that precludes adequate understanding or cooperation; 21. Any previous permanent and nonpermanent cutaneous treatment for aesthetic correction (e.g., ultrasound-based treatments, biomaterial implant, lifting, botulinum toxin injections, laser or intense pulsed light treatment, bio-stimulating treatment, chemical peeling, dermabrasion, fillers) within 6 months prior to study inclusion; 22. Active malignant neoplasm of any type, or history of a malignancy (patients with a history of other malignancies that have been surgically removed and who have no evidence of recurrence for at least five years before study enrollment are also acceptable); 23. Pregnancy or breastfeeding; 24. COVID-19 vaccination within one month prior to study inclusion; 25. Current participation in a similar study or during the previous 3 months.

Locations (3 total)

ASST degli Spedali Civili di Brescia, Brescia, Brescia, Italy
Humanitas Research Hospital, Rozzano, MI, Italy
Campus Biomedico, Roma, Roma, Italy