A Prospective, Randomized, No-treatment Controlled, Evaluator-blinded Clinical Trial to Evaluate the Efficacy and Safety of Polycaprolactone Microspherical Injectable to Improve Forehead Contour

NCT06380972

Status	RECRUITING
Phase	Not Applicable
Sponsor	AQTIS Medical B.V.
Enrollment	189 participants

Key Eligibility Criteria

Inclusion (5)

- e 18 years of age (whichever is the time of signing informed consent) of either sex;
- Subjects who are seeking treatment for forehead contour improvement;
- Subjects with moderate to severe forehead contour deficiency (i.e., ASFS score of 2-3) as evaluated by blinded investigator according to Asian Sloping Forehead Scale (ASFS);
- Subjects who are in good health and suitable for receiving treatment for forehead contour improvement as assessed by the investigator;
- Subjects who are willing to sign informed consent, understand and accept the duration of the study, and are able and willing to comply with all requirements, including scheduled treatment, follow-up, and other study procedures (including clinical photography).

Exclusion (5)

- Those with a history of severe allergy or anaphylactic shock or those with a history of allergy which may result in a response to treatment;
- Those with known allergy to polycaprolactone, carboxymethylcellulose, or any of the ingredients in this product, any local anesthetics such as lidocaine or other amide anesthetics;
- Those with tattoos, scars, deformities, non-healing wounds, active skin disease or skin inflammation (e.g., herpes, acne, eczema, dermatitis, psoriasis, herpes zoster, etc.), abscess, cancer or pre-cancerous lesions and so forth on the forehead that may affect the evaluation of efficacy or increase the risk of treatment;
- Those who have received, or plan to receive during the trial, any permanent filler (e.g., polymethyl methacrylate, organic silicon, expanded polytetrafluoroethylene, etc.), autologous fat or unspecified injectables in the frontal region;
- Those who have received treatment on the forehead such as calcium hydroxyapatite (CaHA), poly-L-lactic acid (PLLA), and polycaprolactone (PCL) within 2 years prior to screening or during the planned trial;

Locations (2 total)

Guangdong Second Provincial General Hospital, Guangzhou, Guangdong, China
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