A Study to Evaluate the Safety and Effectiveness of Injectable Gel for Correction of Infraorbital Hollowing in Chinese Population

NCT06394076

Status	RECRUITING
Phase	Not Applicable
Sponsor	Sinclair Pharmaceuticals Limited
Enrollment	172 participants

Key Eligibility Criteria

Inclusion (6)

- Aged 18 or above (subject to the time of signing the informed consent form) , gender is not limited;
- According to Allergan Infraorbital Rim Scale (AIHS), the subjects were judged by blinded evaluator as having "moderate" or "severe" infraorbital rim hallowing (grade 2-3) in each eye, and both eyes must meet the requirements but do not need to have the same score;
- The injection investigator believes that the hallowing of the infraorbital rim area of the subject can be corrected to grade 0 or grade 1;
- Able and willing to follow the investigator's guidance, following the treatment restrictions in this protocol, and completing all the visits of this trial as required ;
- Able to complete the self-assessment of effectiveness without the use of glasses (contact lenses are accepted if the subject wear contact lenses for all the follow-up visits);

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

Exclusion (5)

- Atrophy in the infraorbital area;
- Previous trauma to the infraorbital area, or residual defects, deformities, or scarring in the periorbital or cheek area before screening;
- The investigator considers that there is a large lower eyelid fat pad that will affect the treatment outcome;
- The front most part of the eyeball protrudes forward more than the front most part of the cheek;
- Hyperpigmentation in the infraorbital area (excluding dark circles which are not caused by hyperpigmentation).

Locations (1 total)

Peking University Third Hospital, Beijing, Beijing Municipality, China