

Submental Fat Reduction by Injection Clinical Trial Inclusion & Exclusion Criteria

Please Read Carefully

Inclusion Criteria

- Healthy males & females age 18 years or older
- Subjects must have a BMI (body mass index) equal to or less than 40
- Subjects must have a double chin without skin laxity (loose skin)
- Subjects must have a history of stable body weight 6 months prior to screening
- If female, subjects must agree to use adequate birth control methods, including but not limited to abstinence, female partner, oral contraceptives, injection, IUD, patch, NuvaRing, condom & spermicide...

Exclusion Criteria

- Subjects that have had any prior procedures to the submental area (i.e. liposuction, surgery, lipolytic agents)
- Subjects with a history of trauma to the chin or neck areas
- Subjects with any conditions that have caused an enlargement to the submental area (i.e. thyroid disease)
- Subjects with a history of or who currently have difficulty swallowing
- Subjects who have participated in another clinical trial within the last 30 days
- Subjects with any other significant medical conditions (respiratory, cardiovascular, hepatic, neurological, or thyroid) that could interfere with the safety of the trial
- Subjects who have received Botox/Dysport or similar injections to the neck or chin within 6 months of the first treatment
- Subjects that have received treatment to the neck or chin area with radio frequency, laser procedures, fillers or chemical peels within 12 months of the first treatment
- Subjects with a sensitivity to topical or local anesthetics (i.e. lidocaine, benzocaine, novocaine)