

# Abdomen Fat Reduction by Injection

## Clinical Trial Inclusion & Exclusion Criteria

### Please Read Carefully

#### Inclusion Criteria

- Healthy male and female candidates who have localized subcutaneous adiposity (fat tissue) and skin elasticity
- Healthy male or female between 18 – 45 years of age who have a history of stable diet and exercise routine in the 3 months prior to screening
- Have a BMI less than 25 kg and have a stable body weight
- Female candidates who have a negative urine pregnancy test, and who use adequate birth control methods

#### Exclusion Criteria

- History of prior treatment of abdominal adipose tissue (e.g. abdominoplasty, liposuction) or exposure to ablative or contouring devices, mesotherapy (injections) or lipolytic agents
- Female subjects who are within 12 months post-partum, who are pregnant, lactating, and/or who are of childbearing potential but not using adequate birth control methods
- Any skin conditions in the treatment area (e.g. psoriasis, eczema, tattoos, striae, Keloid, or hypertrophic or tethered scars, or excessive skin laxity, wrinkles or pannus)
- Planning to embark on a weight loss or exercise program during the study
- Subjects who partake in abdominal massaging & who are willing to discontinue
- Any medical condition that in the opinion of the investigator might jeopardize subjects safety:
  - Any bleeding or connective tissue disorders
  - Asthma, COPD, diabetes, cardiovascular disease (well controlled hypertension is acceptable)
  - History of major surgery within 30 days or planned surgery during study period
  - Lymphatic disease causing lymph edema in the treatment area
  - Abdominal hernias, abdominal asymmetry due to musculoskeletal abnormalities, visible abdominal organomegaly, abdominal recti muscle divarication or diastasis, chronic constipation with abdominal distension
  - History of anorexia nervosa, bulimia, body dysmorphic disorder or any psychiatric disorder related to body image
- Use of anticoagulants (aspirin & NSAIDs), immunomodulators (including steroids), anti-metabolites, adrenergic receptor agonist or blockers non potassium-sparing diuretics prior to Day 1, or during the study
- Use of tricyclic antidepressants or monoamine oxidase inhibitor medications within 14 days prior to Day 1, or during the study
- Any history of major surgery within 30 day to Day 1 or planned surgery during the study period