

PWS Clinical Trial Inclusion & Exclusion Criteria. Please Read Carefully.

Inclusion Criteria

- **Willing to sign informed consent**
- **Healthy males & females older than 18 to 65 years of age**
- **Having a PWS of at least 5 x 5cm**
- **Willing to follow the treatment schedule and post-treatment care**
- **Female candidates only - must be post-menopausal or surgically sterilized, or using a medically acceptable form of birth control at least 3 months prior to enrollment**

Exclusion Criteria

- **PWS on lower legs or hands**
- **Pregnant and/or breastfeeding**
- **Having any electrical implant in the treated area, such as a pacemaker or internal defibrillator**
- **Having a permanent implant in the treated area**
- **History of diseases stimulated by heat, such as recurrent Herpes Simplex in the treated area**
- **Use of non-steroidal anti-inflammatory drugs (NSAIDs, e.g., ibuprofen-containing agents) one week before and after each treatment session**
- **Use of retinoid, antioxidants or medical grade of skin nourishing supplements within 2 months**
- **Having received a facial dermabrasion or chemical peel within 3 months (if face is treated)**
- **Having received treatment with light, radio-frequency or other devices within 6 months of treatment**
- **Having received Botox/collagen/fat injections or other methods of augmentation with injected or implanted material in the treated area within 9 months of treatment**
- **Having undergone a resurfacing procedure, face lift or eyelid surgery within a year of treatment**
- **Having undergone any other surgery in the treated area within 6 months of treatment (or more if skin has not completely healed)**
- **History of keloids scarring or of abnormal wound healing**
- **Suffering from current or history of significant skin conditions in the treated area or inflammatory skin conditions**
- **History of immunosuppressant/immune deficiency disorders (including HIV infection or AIDS)**
- **History of epidermal or dermal disorders**
- **Pigmentary disorders, particularly tendency for hypo- or hyper-pigmentation**
- **Having a known anticoagulative or thromboembolic condition or taking anticoagulation medications one week prior to and during the treatment course**
- **Having undergone any form of treatment for active cancer, or having a history of skin cancer or any other cancer in the areas to be treated, including actinic keratosis, presence of malignant or pre-malignant pigmented lesions**
- **Suffering from significant concurrent illness, such as cardiac disorders, diabetes (type I or II) or pertinent neurological disorders**
- **Tattoo or permanent make up in the treated area**
- **Excessively tanned in areas to be treated or unable/unlikely to refrain from tanning during the study**