Trial record **3 of 3** for:    antria

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**Adipose Derived Stem Cells in Facial Fat Grafting (SVF)**

**This study is currently recruiting participants. (see**[**Contacts and Locations**](https://clinicaltrials.gov/ct2/show/study/NCT02526576?term=antria&rank=3#contacts)**)**

*Verified October 2015 by Antria*

**Sponsor:**

**Antria**

**Information provided by (Responsible Party):**

Antria

**ClinicalTrials.gov Identifier:**

NCT02526576

First received: August 11, 2015

Last updated: October 16, 2015

Last verified: October 2015

https://clinicaltrials.gov/ct2/html/images/frame/triangle.gif**Purpose**

This phase two, randomized, double-blind study is designed to demonstrate the enhanced efficacy of SVF-enriched autologous facial fat grafts, in relation to standard, non-SVF enriched, facial fat grafts by evaluating volumetric retention and contour of the engrafted region over the course of one year.

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| [**Condition**](https://clinicaltrials.gov/ct2/help/conditions_desc) | [**Intervention**](https://clinicaltrials.gov/ct2/help/interventions_desc) | [**Phase**](https://clinicaltrials.gov/ct2/help/phase_desc) |
| Facial Atrophy | Biological: Stromal Vascular Fraction Biological: Biopsy | Phase 2 |

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| Study Type: | Interventional |
| Study Design: | Allocation: Randomized Endpoint Classification: Safety/Efficacy Study Intervention Model: Parallel Assignment Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor) Primary Purpose: Treatment |
| Official Title: | A Phase II Double-blind, Randomized, Study to Assess the Efficacy of Facial Fat Grafts Supplemented With Autologous, Adipose Derived Stromal Vascular Fraction (SVF) |

**Further study details as provided by Antria:**

Primary Outcome Measures:

* Volume retention [ Time Frame: 12 months ] [ Designated as safety issue: No ]

To demonstrate that SVF administration, in concert with autologous facial fat grafts, is more efficacious, with regards to graft survival, than standard, non-SVF enhanced, autologous facial fat grafts

Secondary Outcome Measures:

* Number of Participants ith autologous facial fat grafts via laboratory results [ Time Frame: 36 months ] [ Designated as safety issue: Yes ]

To monitor the safety of SVF administration along with autologous facial fat grafts via laboratory results

* Changes in the quality of skin [ Time Frame: 12 months ] [ Designated as safety issue: No ]

a blinded and independent investigator will assess any changes to the quality of skin

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| Estimated Enrollment: | 34 |
| Study Start Date: | August 2015 |
| Estimated Study Completion Date: | October 2016 |
| Estimated Primary Completion Date: | October 2016 (Final data collection date for primary outcome measure) |

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| [**Arms**](https://clinicaltrials.gov/ct2/help/arm_group_desc) | [**Assigned Interventions**](https://clinicaltrials.gov/ct2/help/interventions_desc) |
| Experimental: Stromal Vascular Fraction  Subjects will receive SVF assisted fat transfer | Biological: Stromal Vascular Fraction  The SVF obtained from adipose tissue will be added to the graft  Other Name: Adiployx  Biological: Biopsy  a subgroup of each arm (2 subjects from each arm) will undergo a fat transfer behind each ear to be removed via biopsy after 12 months |
| Active Comparator: Control -regular fat transfer  Subjects will receive regular fat transfer | Biological: Biopsy  a subgroup of each arm (2 subjects from each arm) will undergo a fat transfer behind each ear to be removed via biopsy after 12 months |

**Detailed Description:**

Human Adipose Tissue is considered as a new source for Stromal Stem Cells and offers a large therapeutic potential for many rare and common diseases that impacts millions of patients worldwide. The Stromal Vascular Fraction (SVF) of Adipose Tissue is relatively easy to extract with minimally invasive procedures such as elective liposuction in large quantities and therefore may be a cost effective source for cellular therapies in a wide range of medical specialties.

The term "Facial Atrophy" describes the lost of subcutaneous fat within the face and can be a result of the aging process as well as some pathological diseases. It can be corrected via autologous fat transfer but usually the majority of the grafted cells will die after 6-12 months. Several publications demonstrate that the addition of SVF cells to the graft may enhance the graft survival.

This double blind, randomized study aims to demonstrated the efficacy of Antria Cell Preparation Process in autologous facial fat grafting.

https://clinicaltrials.gov/ct2/html/images/frame/triangle.gif**Eligibility**

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| Ages Eligible for Study: | 18 Years to 70 Years |
| Genders Eligible for Study: | Both |
| Accepts Healthy Volunteers: | No |

**Criteria**

Inclusion Criteria:

1. Female or Male, Age 18 to 70 years old
2. Subjects that are eligible for liposuction and facial fat grafting procedures for cosmetic purposes and facial atrophy.
3. Subjects must require augmentation to the infra-malar region. Furthermore, facial engraftment to additional, non-study related regions is optional, but not required.
4. Inframalar Atrophy Assessment Scale of 2 to 4
5. Facial volume defect range: 2 to 10 mL
6. Body Mass Index (BMI) between and including 22 and 29
7. Able to understand and provide written and verbal informed consent
8. Fitzpatrick Scale 1 to 6

Exclusion Criteria:

1. Currently taking or have taken None Steroid Anti-inflammatory Drugs (NSAIDs) within last two weeks or corticosteroids within the last six weeks prior to screening
2. Diagnosis of any of the following medical conditions:
   * Active malignancy (diagnosed within 5 years), except for treated non-melanoma skin cancer or other non-invasive or in-situ neoplasm (e.g. cervical cancer)
   * Active infection
   * Type I or Type II Diabetes
   * Skin/Bone deformities in the face, including scaring or hyperpigmentation within the graft site.
3. Subjects who are unlikely to comply with the protocol (e.g., uncooperative attitude, inability to return for subsequent visits, dementia, and/or otherwise considered by the Investigator to be unlikely to complete the study)
4. Subjects with a known drug or alcohol dependence within the past 12 months as judged by the Investigator
5. Dermal fillers or facial reconstruction within the past 24 months, Subjects must also refrain from such procedures during the duration of the study.
6. Subjects with major illnesses involving the renal, hepatic, cardiovascular, and/or nervous systems.
7. Subjects with elevated kidney and/or liver functions
8. Any other disease condition or laboratory results that in the opinion of the investigator may be clinically significant and render the subject inappropriate for the study procedure(s), may alter the accuracy of study results, or increase risk for subjects.
9. Subjects with life-expectancies less than 9 months
10. Subjects with known collagenase allergies
11. Subjects with idiopathic or drug-induced coagulopathy
12. Pregnant females
13. On radiotherapy or chemotherapy agents
14. Taking strong CYP450 inhibitors
15. Subjects with a history of keloids or hypertrophic scar formations
16. Previous treatment with any synthetic fillers in the inframalar area

https://clinicaltrials.gov/ct2/html/images/frame/triangle.gif**Contacts and Locations**

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see [Learn About Clinical Studies.](https://clinicaltrials.gov/ct2/about-studies/learn)   
  
Please refer to this study by its ClinicalTrials.gov identifier: NCT02526576

**Contacts**

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| Contact: Shah Rahimian, MD | 7243490520 | [srahimian@**antria**.org](mailto:srahimian%40antria.org?subject=NCT02526576,%20SSVF0002,%20Adipose%20Derived%20Stem%20Cells%20in%20Facial%20Fat%20Grafting) |  |
| Contact: Sarah Boyer | 7243490520 | [sboyer@**antria**.org](mailto:sboyer%40antria.org?subject=NCT02526576,%20SSVF0002,%20Adipose%20Derived%20Stem%20Cells%20in%20Facial%20Fat%20Grafting) |  |

**Locations**

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| **United States, Pennsylvania** | |
| Delmont Surgery Center | **Recruiting** |
| Delmont, Pennsylvania, United States, 15601 | |
| Contact: Shah Rahimian, MD    724-349-0520    [srahimian@antria.org](mailto:srahimian%40antria.org?subject=NCT02526576,%20SSVF0002,%20Adipose%20Derived%20Stem%20Cells%20in%20Facial%20Fat%20Grafting) | |
| Contact: Sarah Boyer    7243490520    [sboyer@antria.org](mailto:sboyer%40antria.org?subject=NCT02526576,%20SSVF0002,%20Adipose%20Derived%20Stem%20Cells%20in%20Facial%20Fat%20Grafting) | |
| Principal Investigator: Francis Johns, MD | |

**Sponsors and Collaborators**

**Antria**

**Investigators**

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| Study Director: | Shah Rahimian, MD | **Antria** |  |

https://clinicaltrials.gov/ct2/html/images/frame/triangle.gif**More Information**

No publications provided

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| Responsible Party: | Antria |
| ClinicalTrials.gov Identifier: | [NCT02526576](https://clinicaltrials.gov/show/NCT02526576)     [History of Changes](https://clinicaltrials.gov/ct2/archive/NCT02526576) |
| Other Study ID Numbers: | SSVF0002 |
| Study First Received: | August 11, 2015 |
| Last Updated: | October 16, 2015 |
| Health Authority: | United States: Food and Drug Administration |

Keywords provided by Antria:

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| Facial Atrophy Autologous Adult | Adipose Derived Stem Cells Stromal Vascular Fraction Collagenase |

Additional relevant MeSH terms:

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| Facies Disease Attributes Pathologic Processes |  |

ClinicalTrials.gov processed this record on October 30, 2015