

# A Phase I/II Study of Autologous Fat Transfer for Scar Prevention and Remodeling

**This study is currently recruiting participants.**

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<b>Sponsor:</b>	<b>University of Virginia</b>
<b>Participating Sites:</b>	<b>University of Virginia</b>
<b>ClinicalTrials.gov Identifier:</b>	<b>NCT01119326</b>

## **Purpose**

This study is designed to test the safety and feasibility of using AFT (Autologous fat transfer) to favorably impact the formation and remodeling of scar tissue that forms in association with wounds that heal either by secondary intention or with the use of split thickness skin grafts (STSG).

## **Objectives**

### Primary Objectives:

1. To determine the safety and feasibility of using AFT in early and delayed treatment settings to positively enhance the quality and appearance of overlying scar.
2. To determine the safety and impact of AFT “dose” on scar quality and appearance.

### Secondary Objective:

1. To determine the correlation of subjective and objective scar assessment tools for serial, prospective scar analysis.

## Study Design

### Phase I:

The safety and effect of a given AFT “dose” is currently unknown in the context of scar prevention and remodeling. In the first phase of this pilot study, we intend to explore the safety of increasing doses of AFT treatment independently in both the Early AFT subgroup and the Delayed AFT subgroup. For each subgroup, patients will be treated with one of 3 AFT doses, based on the timing of their enrollment within the study. The 3 AFT doses that will be used during the study are:

- 1) 0.2ml of adipose tissue/cm<sup>2</sup> of scar (10ml maximum per site)
- 2) 0.5ml/cm<sup>2</sup> (25ml maximum per site)
- 3) 1ml/cm<sup>2</sup> (50ml maximum per site).

Treatment will start with the lowest dose listed. A minimum of 3 subjects will be enrolled. If no Dose Limiting Toxicity (DLT) is observed in any of the 3 subjects, dose escalation to the next dose level will occur upon approval by the Medical Monitor and/or Study Coordinator. If 1 DLT is observed in the first cohort of 3 subjects, enrollment to that dose level will be expanded to 6 subjects. If no additional DLTs are observed, dose escalation to the next dose level will occur upon approval by the Medical Monitor and/or Study Coordinator. If any additional DLTs are observed, enrollment to that dose level will stop, and the next lower dose level will be considered the Maximum Tolerated Dose (MTD), as long as a minimum of 6 subjects were enrolled to the next lower dose level and no more than 1 DLT was observed in those six subjects. If 6 subjects have not been enrolled to the next lower dose level, then enrollment should resume at that dose level until 6 subjects have completed the DLT evaluation period (14 days post treatment).

Enrollment will occur simultaneously to both the Early AFT and Delayed AFT subgroups. Dose escalation will occur independently for each of the subgroups.

### Phase II:

The MTD will be determined independently for each of the 2 subgroups. Once the MTD has been determined, a total of 20

subjects will be enrolled at the MTD (including the 6 subjects enrolled to that dose level during the MTD determination process) for each subgroup to obtain efficacy data. If the MTD is reached in one subgroup prior to the other, MTD expansion may occur in that group while MTD determination is ongoing in the other subgroup.

## **Eligibility**

### Inclusion Criteria:

1. At least 2 separate (i.e. non-contiguous) or 1 large wound/scar previously healed by placement of a STSG and/or by secondary intention ("study sites"), each  $\leq 80\text{cm}^2$  in size (area).
  - The study sites should be similar in size and anatomical location (e.g. upper arms; trunk; legs) to the extent practically possible
2. Adequate adipose depot for tissue harvest
3. For Early AFT Subgroup:
  - treatment of study sites with AFT as soon as medically reasonable after definitive closure(STSG) or healing (secondary closure) of such sites, as determined by, and based on the clinical assessment and judgment of treating physician, but no later than 3 months after date of closure.

For Delayed AFT Subgroup:

- treatment of study sites with AFT at least 6 months after definitive closure(STSG) or healing (secondary closure) of such sites.
4. Age range: 18-65 years
  5. Negative pregnancy test
  6. Able and willing to provide verbal and written informed consent.
  7. Subject should begin protocol initiation within 2 weeks of being enrolled.

### Exclusion Criteria:

1. Sepsis

2. Life or limb-threatening injury/disease
3. Prior history of non-compliance
4. Active drug use/abuse
5. Active psychiatric illness, except depression (unless patient is currently being treated for suicidal intentions)
6. Pregnancy
7. Active cancer, or new diagnosis of cancer within the past 5 years, with the exception of basal cell and squamous cell carcinomas, as long as the subject is disease free at the time of enrollment and that the previous diagnosis was not at a site to be treated by AFT.
8. History of bleeding tendency/inability to clot, and/or INR  $\geq$  2.2
9. Life-threatening allergic reaction to one of the medications/agents to be used in the study with no acceptable alternative/substitute identifiable
10. Recent (within the past month) *differential* (e.g. one site treated with steroids, the other not) treatment of targeted study sites by steroid injections, pressure garments, silicone sheeting or other similar scar management modalities.
11. Incarceration.

## **Enrollment Information**

Estimated Enrollment: 52

Study Start Date: April 2010

Estimated Completion Date: April 2012

## **Contacts**

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## **Autologous Fat Transfer for Scar Prevention and Remodeling**

The purpose of this study is to use a procedure in which tissue (adipose or fat) taken from other parts of your body is transplanted into your wound to see if it will improve the quality and appearance of the scar from your wound. This procedure is called autologous fat transfer (AFT). If you have one or more displeasing scars on your body, or have a wound that is anticipated to heal with a displeasing scar then you may qualify for the study.

The study involves an outpatient surgery procedure that will include anesthesia that puts you to sleep. You will have 2 treatment sites identified for AFT in this study. Both treatment sites will be similar in size and location on your body. One of these sites will be treated using the AFT procedure the other will be treated using a fake procedure (placebo procedure). You will need to be seen in the clinic 2 weeks, 1 month, 3 months, 6 months, and 12 months after your AFT procedure to assess the scar.

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[http://www.healthsystem.virginia.edu/internet/clinical\\_trials/categories.cfm?cat=25&category=Healthy%20Subjects%20-%20Outpatient](http://www.healthsystem.virginia.edu/internet/clinical_trials/categories.cfm?cat=25&category=Healthy%20Subjects%20-%20Outpatient)

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