Pilot Study Investigating the Efficacy of Fat Grafting as a Treatment for Male and Female Facial Acne Scarring

NCT04559022

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1. Introduction and Purpose

1.1 Purpose

This single-center, clinical trial consists of a one autologous fat grafting treatment followed by 3-month and 6-month post-treatment visits in order to assess the efficacy of fat grafting when used by men and women with facial acne scars.

1.2 Primary Objectives

Objective 1: To assess the efficacy and tolerability of the autologous fat grafting when used on men and women with acne scars on the face. [redacted] Finally, both the clinician's and subject's assessment will be characterized using a clinician assessment scale at the 3-months and 6-month post-treatment visits.

[redacted]

1. Background

Acne vulgaris is a chronic inflammatory condition that can result in permanent scarring. There are a number of modalities currently in use or under investigation for the treatment of atrophic acne scars. [redacted] Autologous fat has gained increasing popularity, as there is no risk of allergic reaction, since the fat is derived directly from the patient.

This is a single-site, pilot study at UT Southwestern Medical Center at Dallas in the Department of Plastic Surgery assessing the clinical effects of autologous fat grafting for the treatment of facial acne scarring. The Principal Investigator has been selected based on his expertise, qualifications (credentials, training, and medical specialty), subject access, previous clinical research, facilities, and interest in this particular field of research.

2. Concise Summary of Project:

3.1 Objective

This investigation, pilot study will evaluate the safety and efficacy of autologous fat grafting for the treatment of acne scarring. [redacted]

3.2 Clinical Study

Autologous Fat Grafting to the Face for the Treatment of Acne Scars

This is a single-site, non-randomized, non-controlled study designed to follow at least fifteen (15) qualified and consenting subjects receiving 1 treatment of autologous fat grafting to acne scars present on the face. [redacted]

This is a single-site study at UT Southwestern Medical Center at Dallas in the Department of Plastic Surgery. The Principal Investigator has been selected based on his expertise, qualifications (credentials, training, and medical specialty), subject access, previous clinical research, facilities, and interest in this particular field of research. Subjects will be identified from Dr. Jeffrey Kenkel's clinical practice at the University of Texas Southwestern Medical Center. Subjects will be numbered sequentially in the order in which they qualify for entry into the study.

[redacted]

[redacted]

Biopsies will be taken using 0.33mm WellTech Rapid Core 0.33mm Biopsy Punch. Biopsies will allow investigators to correlate changes seen in skin measurements with histology and gene expression. Time for two biopsies will take approximately five minutes.

[redacted]

3. Subject Enrollment

4.1 Informed Consent Form

[redacted]

4.2 Subject Identification

[redacted]

4.3 Eligibility Criteria

Inclusion Criteria

1. Men and women 18 to 60 years of age having general good health.

2. Individuals deemed by the Investigator to have a significant amount acne scarring on the face and that desire correction of this condition.

3. [redacted]

[redacted]

4. [redacted]

5. [redacted]

6. [redacted]

Exclusion Criteria

1. Individuals diagnosed with known allergies to general skin care products.

2. Individuals who have presence of an active systemic or local skin disease that may affect wound healing.

3. Individuals with sensitivity to topical lidocaine.

4. [redacted]

5. [redacted]

6. [redacted]

7. [redacted]

8. [redacted]

9. [redacted]

10. [redacted]

11. [redacted]

12. [redacted]

13. [redacted]

14. [redacted]

15. [redacted]

16. [redacted]
    - [redacted]
    - [redacted]
        - [redacted]
        - [redacted]
        - [redacted]
        - [redacted]
    - [redacted]
    - [redacted]
    - [redacted]
    - [redacted]
    - [redacted]

17. [redacted]
    - [redacted]
    - [redacted]
    - [redacted]
    - [redacted]
    - [redacted]
    - [redacted]

18. [redacted]

19. [redacted]
20. [redacted]
21. [redacted]
22. [redacted]
23. [redacted]
24. Individuals who have any condition, which in the opinion of the Investigator makes the patient unable to complete the study per protocol (e.g. patients not likely to avoid other cosmetic treatments to the treatment area; patients not likely to stay in the study for its duration because of other commitments, concomitant conditions, or past history; patients anticipated to be unreliable, or patients who have a concomitant condition that may develop symptoms that might confuse or confound study treatments or assessments).

4.4 Subject Instructions

- [redacted]
- [redacted]
- [redacted]
- [redacted]

- [redacted]

Study Design

5.1 Outline of Procedures

Procedures/Time Points:	**Visit 1** **Screening/Baseline (-14 to 0 day[s])**	**Visit 2** **Day 1 (± 3 days)**	**Visit 3** **3-months post-treatment (± 3 days)**	**Visit 4** **6-months post-treatment (± 3 days)**
ICF, and qualification/enrollment paperwork	X			
Urine pregnancy test	X			
Physical Examination of Acne Scarring	X			
Treatment of facial acne scars		X		
Non-Invasive Procedures (Aquaflux, BTC-2000, DUB, OCT)		X	X	X
Biopsies		X	X	X
Error! Reference source not found. (Miravex, VISIA, and Standard Photography)		X	X	X
Error! Reference source not found.			X	X
Error! Reference source not found. Evaluation and CGAIS			X	X

[redacted]

1. [redacted]
2. [redacted]
3. [redacted]

5.3 Screening: Visit 1 (-14 to 0 day[s])

1. [redacted]
2. [redacted]

[redacted]

3. [redacted]
4. [redacted]
5. [redacted]

This visit will take 30-45 minutes. This visit may be conducted at the same time as Visit 2, the first treatment.

5.4 Treatment Visit: Visits 2 (Day 1)

1. [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. [redacted]
   a. [redacted]
   b. [redacted]
   c. [redacted]
   d. [redacted]
6. [redacted]

[redacted]

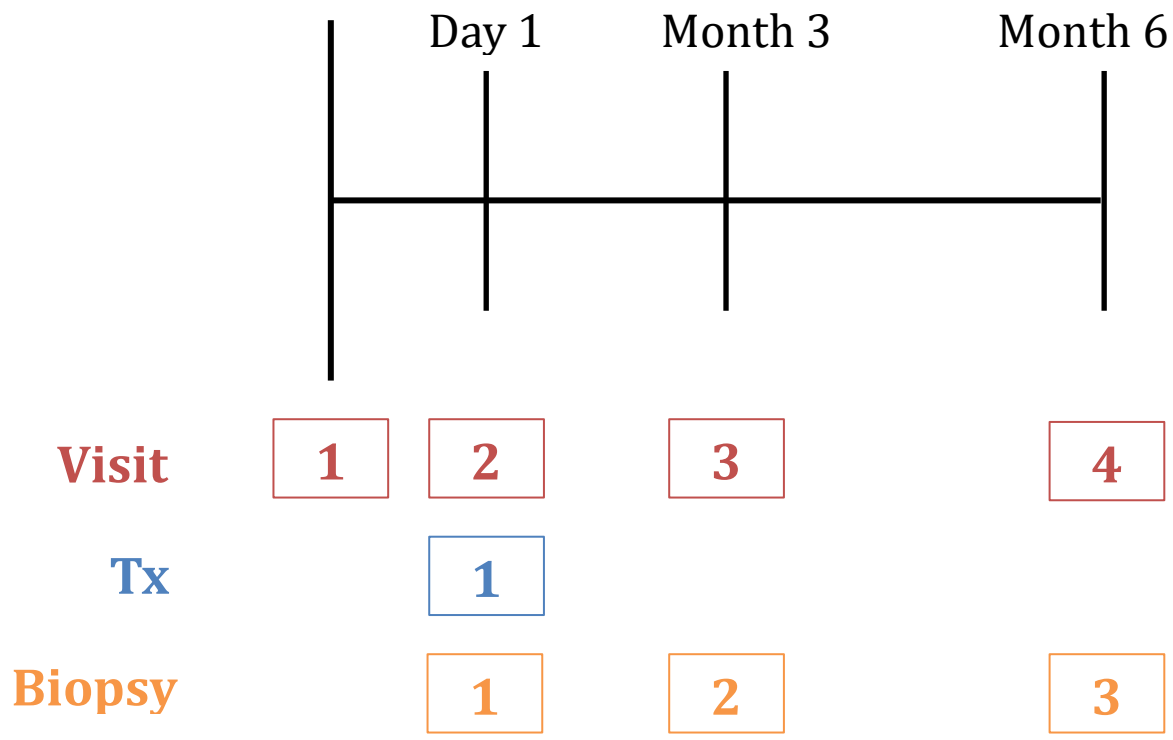
These visits will take approximately 2 hours.

[redacted]

5.5 Post-Treatment Visits: Visit 3 (3-Months Post-Treatment) and Visit 4 (6-Months Post-Treatment)

1. [redacted]
2. [redacted]
3. [redacted]
    - [redacted]
    - [redacted]
    - [redacted]
    - [redacted]

These visits will take about 45 minutes.



5.6 Event Follow-up Visits (Investigator or designee)

[redacted]

6. Assessments

6.1 Global Aesthetic Improvement Assessments

6.1.1 Clinician's Global Aesthetic Improvement Scale (CGAIS)

Rating	Description
1	**Very Much Improved:** Optimal cosmetic result in this subject.
2	**Much Improved:** Marked improvement in appearance from the initial

	condition, but not completely optimal for this subject.
3	**Improved:** Obvious improvement in appearance from initial condition, but a re-treatment is indicated.
4	**No Change:** The appearance is essentially the same as the original condition.
5	**Worse:** The appearance is worse than the original condition.

6.1.2 Subject Global Aesthetic Improvement Scale (SGAIS)

Rating	Description
1	**Very Much Improved:** Optimal cosmetic result.
2	**Much Improved:** Marked improvement in appearance from the initial condition, but not completely optimal.
3	**Improved:** Obvious improvement in appearance from initial condition.
4	**No Change:** The appearance is essentially the same as the original condition.
5	**Worse:** The appearance is worse than the original condition.

6.2 Photography Procedures

[redacted]

1. NIKON D7200

[redacted]

2. VISIA Complexion Analysis

[redacted]

[redacted]

[redacted]

3. Miravex 3D Imaging

[redacted]

6.3 Blinded Evaluation

[redacted]

7. Sources of Research Material

Medical history (age, sex, skin type, recent sun exposure, allergies, current medications, major illnesses), standard photography, VISIA images, Miravex images, OCT images, high frequency ultrasound images, TEWL measurements, BTC 2000 measurements, biopsies, evaluations, responses to questionnaires, adverse events and treatment.

8. Recruitment Methods and Consenting Process

[redacted]

[redacted]

[redacted]

9. Potential Risks

Bruising and Infection: (Rare < 1%)

[redacted]

Transient edema and/or erythema: (Occasionally < 3%)

[redacted]

Undercorrection/overcorrection/contour Irregularities: (Rare < 1%)

[redacted]

Scarring: (Rare < 1%)

[redacted]

Allergic Reaction: (Rare < 1%)

[redacted]

Biopsy

[redacted]

Photography

[redacted]

[redacted]

10. Adverse Events

10.1 Definition of an Adverse Event

[redacted]

[redacted]

10.2 Definition of a Serious Adverse Event

[redacted]

10.3 Procedures for Reporting Adverse Events

[redacted]

10.4 Medical Treatment for Adverse Events and Serious Adverse Events

[redacted]

10.5 Unanticipated Adverse Reactions

[redacted]

10.6 Anticipated Reactions

[redacted]

[redacted]

[redacted]

11. Attrition

[redacted]

[redacted]

12. Procedures to Maintain Confidentiality:

[redacted]

[redacted]

[redacted]

[redacted]

14. Biostatistics:
This initial study will include descriptive statistics from baseline analysis.

[redacted]

[redacted]

15. References

1. Goodman GJ, Baron JA. Postacne scarring—a quantitative global scarring grading system. J Cosmet Dermatol. 2006;5:48-52.
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