ISRCTN64292493 https://doi.org/10.1186/ISRCTN64292493

Improving facial scars: comparing two fat grafting techniques using a nanofat graft

Submission date
14/04/2024

Recruitment status
No longer recruiting

Registration date
22/04/2024

Overall study status
Completed

Last Edited
22/04/2024

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Despite the variety of therapeutic techniques used to improve the appearance of disfiguring scars, there is still no method that achieves perfect results, and nanofat injections have shown clinical benefits in rejuvenating the skin and improving the appearance of scars. Additionally, the concurrent use of platelet-rich fibrin with nanofat has shown an enhanced effect.

Who can participate?
Patients aged 18 years old and over with atrophic linear facial scars

What does the study involve?
This study compares two groups of patients with atrophic facial scars. A control group will receive nanofat grafting and in contrast, the experimental group will receive unfiltered nanofat grafting with platelet-rich fibrin.

What are the possible benefits and risks of participating?
One of the features of nanofat grafting is the regeneration and improvement of the scar's texture and color in terms of pigmentation, restoring its thickness to the normal proportion of the surrounding skin. It is a safe, easy, and effective method due to its high content of adipose-derived stem cells. However, this method has several limitations, including the presence of a donor surgical site and consequent complications such as pain, swelling, and infection.

Where is the study run from?
Oral and Maxillofacial Surgery Hospital, Faculty of Dentistry, Damascus University, Syria

When is the study starting and how long is it expected to run for?
January 2021 to January 2024

Who is the funding of the study?
Investigator initiated and funded

Who is the main contact?
Dr Mhd Anas Alnemr, anas.alnmer@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Mhd Anas Alnemr

ORCID ID
https://orcid.org/0009-0002-9047-3030

Contact details
Mezzeh Highway
Damascus
Syria
0000
+963957432950
anas1.alnmer@damascusuniversity.edu.sy

Type(s)
Public

Contact name
Dr Mhd Anas Alnemr

Contact details
Mezzeh Highway
Damascus
Syria
0000
+963957432950
anas.alnmer@gmail.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
The management of facial scars by using unfiltered nanofat graft mixed with platelet-rich fibrin or conventional nanofat graft

Study objectives

The use of nanofat mixed with platelet-rich fibrin is effective in the management of atrophic facial scars compared to conventional nanofat.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 21/03/2021, Ethics Scientific Committee at Damascus University (Oral and Maxillofacial Surgery Department - Faculty of Dental Medicine - Damascus University, Damascus, 4671, Syria; +963 11 33923011; verification.dicr@damascusuniversity.edu.sy), ref: DN-210224-11-H8

Study design
Single-blind randomized controlled clinical trial

Primary study design
Interventional

Study type(s)
Treatment, Efficacy

Health condition(s) or problem(s) studied
Improving the appearance of atrophic facial scars in patients

Interventions
This study is a randomized controlled trial, including 2 groups of patients with atrophic facial scars - the control group will receive nanofat grafting. In contrast, the experimental group will receive unfiltered nanofat grafting with platelet-rich fibrin (PRF). Participants will be randomized into 2 groups using https://www.randomizer.org/.

The follow-up for each patient is 6 months with 3 visits for each patient:
1. One week postoperative
2. 3 months postoperative
3. 6 months postoperative

The primary outcome of the study is assessed using the Patient And Observer Scar Assessment Scale (POSAS) in 2 parts, firstly by 3 observers and secondly by the patient himself/herself. The observers will assess scar quality (vascularity, pigmentation, thickness, relief, pliability and surface area) on a scale from 1 to 10. While the patient will assess according to the following parameters from 1 to 10: pain, itchiness, color, stiffness, thickness and irregularity.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Scar quality from the perspectives of the patient and the clinician measured using the Patient And Observer Scar Assessment Scale (POSAS) at baseline (T0: preoperative), 3 (T1) and 6 (T2) months postoperative

Key secondary outcome(s))

The following secondary outcome measures will be assessed at baseline (T0: preoperative), 3 (T1) and 6 (T2) months postoperative:
1. Scar appearance measured in 4 grades (Level 1: Macular Scar; Level 2: Mild Scar; Level 3: Moderate Scar; and, Level 4: Severe Scar) by 3 observers using the Goodman and Baron Scale
2. Aesthetic improvement measured using the Global Aesthetic Improvement Scale (7 levels: -3 = Very Much Worse; -2 = Much Worse; -1 = Worse; 0 = No Change; 1 = Improved; 2 = Much Improved; and, 3 = Very Much Improved)

Completion date
20/01/2024

Eligibility

Key inclusion criteria
1. Patients with atrophic linear facial scars
2. The length of the scar is more than 2 centimeters
3. Patients older than 18 years old
4. No systemic disease and syndromes
5. Previously untreated scars

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
21 years

Upper age limit
47 years

Sex
All

Total final enrolment
24

Key exclusion criteria
1. Patients with acute skin disease
2. Patients with bleeding disorder
3. Patients has gone through severe weight gain/loss during the past few months
4. Skinny patients (does not have enough fat tissue in the donor sites)

Date of first enrolment
01/03/2022

Date of final enrolment
01/03/2023

Locations

Countries of recruitment
Syria

Study participating centre
Oral and Maxillofacial Surgery Hospital, Faculty of Dentistry, Damascus University
Mazzeh Highway
Damascus
Syria
4671

Sponsor information

Organisation
Damascus University

ROR
https://ror.org/03m098d13

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			22/04/2024	No	Yes