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Autologous fat injections to improve wound scars

Submission date 02/12/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 04/12/2024	**Overall study status** Completed	
Last Edited 04/12/2024	**Condition category** Other	

Plain English summary of protocol

Background and study aims
This study aims to evaluate how effective unfiltered nanofat graft injections are in healing wounds and managing facial scars. Researchers are interested in understanding how well these fat injections work and how acceptable they are to patients.

Who can participate?
Participants must be over 18 years old, in good health, and have recently undergone facial surgery for specific types of jaw fractures. The wound from the surgery must be at least 4 cm long. Participants must also agree to complete all procedures and attend follow-up appointments.

What does the study involve?
Participants will have fat extracted from their lower abdomen using a special procedure. This fat is then processed into a nanofat emulsion and injected under the skin near the surgical wound. The area is then bandaged. Follow-up visits will occur after one week, one month, three months, and six months to monitor healing and take photographs under consistent conditions.

What are the possible benefits and risks of participating?
The potential benefit is improved wound healing and scar management. Risks may include typical surgical risks such as infection, discomfort, or adverse reactions to the procedure.

Where is the study run from?
Damascus University (Syria)

When is the study starting and how long is it expected to run for?
May 2023 to May 2025

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Evaluation the efficacy of unfiltered nanofat graft injection on wound healing for facial scar management

Study objectives
Knowing the effectiveness of autologous fat injections in healing wounds, and the extent of the patient’s acceptance of them

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 26/11/2024, Biomedical Research Ethics Committee at Damascus University (Mazzeh highway, Damascus, -, Syria; +963-11-33923192; info@damascusuniversity.edu.sy), ref: DN-261124-352

Study design
Randomized controlled trial-split scar

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital, University/medical school/dental school

Study type(s)
Quality of life, Treatment, Efficacy

Participant information sheet

Health condition(s) or problem(s) studied
Wound healing

Interventions
After cleaning procedures for the lower abdomen with povidone 5%, the fat will be extracted from the abdominal area, as modified Klein solution is first injected. Fat is extracted by inserting a special cannula for extracting microscopic fat that has the following characteristics (a 3 mm multi-hole cannula with a hole size of 1 mm) connected to a retracting syringe. Negative pressure is applied to extract the fat into the syringe.
The extracted grease is then washed with serum and filtered. These greases are called micro-emulsification. Then a mechanical emulsification process is performed by using two 20cc syringes connected to each other with a luer-lok conveyor. After performing 30 alternating movements, the grease turns into an emulsion with a watery consistency with a yellow color. For white, here we have unfiltered nanofat .
After suturing the skin in layers to prevent tension on both ends of the wound and delay healing, the product is injected directly under the skin in the area of the surgical incision using a 27-G cannula (0.5 ml of product within 2 cm of the wound).
Finally, place a clean, sterile bandage over the area.
This work is performed by one surgeon.

Follow-up will take place after a week, a month, and follow-up taking photographs after 3 months and 6 months of working with the same photography conditions, lighting and distance, and using the POSAS sensor to evaluate scars.

Intervention Type
Procedure/Surgery

Primary outcome measure
(POSAS) Patient and Observer Scar Assessment Scale at a week, a month, and follow-up after 3 months and 6 months

Secondary outcome measures
The Global Aesthetic Improvement Scale (GAIS) at a week, a month, and follow-up after 3 months and 6 months

Overall study start date

24/05/2023

Completion date
24/05/2025

Eligibility

Key inclusion criteria
1. Patients over the age of 18 years
2. Patients in good health condition
3. Patients who underwent recent facial surgery through the two surgical entrances under the jaw and under the chin, for reduction and fixation
Fractures of the symphysis, parasymphysis, and fractures of the body and angle of the mandible, provided that they are non-open fractures
4. The length of the wound is at least 4 cm
5. Patients who agreed to complete all procedures and attend the scheduled appointments for follow-up sessions

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Male

Target number of participants
14

Total final enrolment
14

Key exclusion criteria
1. Patients who have allergic soil
2. Pregnant or breastfeeding women
3. Patients with a history of alterations
4. Arthritis
5. The presence of infection
6. Spastic asthenia patients
7. Patients with a history of radiation or chemotherapy within less than six months
8. Patients with a history of weight gain or loss in the previous months.
9. Thin patients (those who do not have enough fat in the sites are an exception)

Date of first enrolment
24/12/2023

Date of final enrolment
24/12/2024

Locations

Countries of recruitment
Syria

Study participating centre
Damascus university
Damascus city center
Damascus
Syria
-

Sponsor information

Organisation
Damascus University

Sponsor details
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Sponsor type
University/education

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http://www.damascusuniversity.edu.sy

ROR
https://ror.org/03m098d13

Funder(s)

Funder type

University/education

Funder Name
Damascus University

Alternative Name(s)
University of Damascus, , DU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Syria

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
01/01/2025

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication