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The effectiveness of platelet-rich plasma injection in the treatment of forehead wrinkles

Submission date
03/10/2024

Recruitment status
No longer recruiting

Registration date
04/10/2024

Overall study status
Completed

Last Edited
04/10/2024

Condition category
Skin and Connective Tissue Diseases

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

Plain English summary of protocol
Background and study aims
Wrinkles are considered one of the most common signs of ageing and interventions aimed at treating them are among the most common interventions in cosmetic clinics that pose a challenge to the doctor. A number of materials have been used in treating wrinkles, each of which has advantages and disadvantages. Microneedling has been used in treating wrinkles and skin problems such as pigmentation and scars because it stimulates the formation of collagen. Therefore, this study aimed to increase the effectiveness of microneedling by combining it with platelet-rich plasma injections.

Who can participate?
Women aged 30 - 50 years with forehead wrinkles

What does the study involve?
Participants were randomly divided into two groups. The first group underwent three sessions of microneedling using the Dermapen device with 21-day time intervals between sessions. The second group underwent three sessions of microneedling using the Dermapen device followed by platelet-rich plasma injections with 21-day time intervals between sessions. The results were then compared by a committee of specialists at 6 months after the last intervention.

What are the possible benefits and risks of participating?
The possible benefits are the improvement of wrinkles. There are no expected risks but some pain and edema (swelling) could happen in some cases.

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 December 2024

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Dr Ahmad Aleed, ahmadaleed004@gmail.com

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
DN-02092024-307

Study information

Scientific Title
Evaluation of the effectiveness of platelet-rich plasma injection after microneedling by Dermapen device in the treatment of forehead wrinkles

Acronym
EPMW

Study objectives
Dermpen is effective at treating wrinkles

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 19/05/2023, Damascus University Biomedical Research Ethics Committee (Damascus, Damascus, 12110, Syria; +963 (0)1133923482; ap.srd@damascusuniversity.edu.sy), ref: DN-02092024-307

Study design
Double-blind randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Dental clinic, Hospital

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

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Forehead wrinkles

Interventions
The research sample was divided into two groups using a coin method. The first group underwent three sessions of microneedling using the Dermapen device with 21-day time intervals between sessions, which is the control group. The second group underwent three sessions of microneedling using the Dermapen device, followed by platelet-rich plasma injections with 21-day time intervals between sessions, which is the study group. The results were then compared by a committee of five specialists at 6 months after the last intervention.

Intervention Type
Mixed

Primary outcome measure
Wrinkle grade is measured using the Allergan Forehead Line scale at baseline and 6 months after the last intervention

Secondary outcome measures
Improvement measured using the Subject Global Aesthetic Improvement Scale (SGAIS) at baseline and 6 months after the last intervention

Overall study start date
19/05/2023

Completion date
30/12/2024

Eligibility

Key inclusion criteria
1. Female
2. 30 - 50 years

Participant type(s)
Patient, Other

Age group
Adult

Lower age limit
30 Years

Upper age limit
50 Years

Sex
Female

Target number of participants
16

Total final enrolment
20

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
25/09/2023

Date of final enrolment
22/06/2024

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Damascus
Damascus
Syria
12110

Sponsor information

Organisation
Damascus University

Sponsor details
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Sponsor type
University/education

Website
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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
30/12/2024

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

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