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Developing a reproducible procedure for optimal utilization of platelet-rich plasma and platelet-rich fibrin in aesthetic treatments

Submission date
18/01/2024

Recruitment status
No longer recruiting

Registration date
22/01/2024

Overall study status
Completed

Last Edited
22/01/2024

Condition category
Other

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

Plain English summary of protocol

Background and study aims
This research aims to show how injections of autologous platelet-rich plasma (C-PRP, PRP LCC) and platelet-rich fibrin (I-PRF, F-PRF) can enhance skin quality in specific facial areas within aesthetic medicine. The study focuses on using user-friendly Plasmoo kits (https://www.plasmoo.pl), simplifying the treatment process. The main goal is to make the most of an individual's blood for better aesthetic treatments, ensuring they work well and are satisfying for participants. This approach could be a promising direction for future aesthetic medicine treatments, making them more effective and convenient.

Who can participate?
Healthy female volunteers aged between 30-60 years old who are seeking facial skin rejuvenation

What does the study involve?
This research consists of two phases: a lab stage and a clinical stage. In the lab phase, efforts are made to enhance the process of spinning blood to obtain optimal platelet-rich plasma (PRP) for aesthetic procedures. Moving to the clinical phase, blood is drawn from 20 volunteers, processed differently, and injected into their facial skin using mesotherapy. Skin changes are monitored over time using high-frequency ultrasonography.

Measurements are taken before the study begins and one month after each treatment, focusing on skin thickness, collagen, and elastin fibers. These observations are essential for understanding how the treatment affects the skin. The research team will use a Global Aesthetic Improvement Scale (GAIS) to assess aesthetic changes a month after the third treatment. The scale ranges from 0 (worse) to 4 (very much improved). Participants will also express their personal satisfaction levels (very satisfied, satisfied, not satisfied) after each treatment and indicate if they would recommend the procedure to friends.

What are the possible benefits and risks of participating?
Benefits for patients:

1. Access to new treatment method
2. Professional monitoring of the skin condition
3. Contribution to research
4. Potential Improvement in appearance

Risks for patients:
1. Ineffectiveness, not achieving the desired aesthetic outcome
2. Physical discomfort - transient side effects (bruising, swelling)
3. Psychological impact - unmet expectations may lead to disappointment
4. Time commitment (treatment, follow-up visits)

Where is the study run from?
ESME Clinic (Poland)

When is the study starting and how long is it expected to run for?
February 2019 to June 2021

Who is funding the study?
Innmedis (Poland)

Who is the main contact?
Dr Lidia Majewska, drlmajewska@gmail.com (Poland)

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
Developing a reproducible procedure for optimal utilization of platelet-rich plasma (PRP) and platelet-rich fibrin (PRF) in aesthetic treatments: efficacy evaluation using ultrasound imaging. Single-center prospective open-label randomized study

Study objectives
This single-center prospective open-label randomized study aims to achieve a repeatable procedure for isolating platelet-rich plasma, with a focus on achieving the highest possible platelet recovery and platelet concentration parameters from the collected material and to assess the effectiveness of autologous platelet-rich plasma (C-PRP, PRP LCC) and platelet-rich fibrin (I-PRF, F-PRF) injections on skin density and thickness in facial aesthetic treatments.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 24/09/2020, Bioethics Committee of the Jagiellonian University in Krakow (Grzegorzecka 20, Krakow, 31531, Poland; +48124332739; kbet@cm-uj.krakow.pl), ref: 1072.6121.11.2020

Study design
Single-center prospective open-label randomized study

Primary study design
Interventional

Secondary study design
Randomized study

Study setting(s)
Laboratory, Medical and other records

Study type(s)
Treatment, Efficacy

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Improving aging skin density and thickness by injecting different types of autologous plasma preparations.

Interventions

This study consists of two stages: a laboratory phase and a clinical phase. In the first stage, the laboratory tests aim to optimize the parameters (time and speed) of whole blood centrifugation, allowing for the best possible product (PLT concentration and PLT recovery) to be obtained for use during aesthetic medicine procedures involving autologous platelet-rich plasma and fibrin. In the clinical phase of the study, after collecting 20 mL of blood from each participant into two tubes – with and without anticoagulant – the preparations will be injected using the mesotherapy method into the facial skin of 20 volunteers participating in the study. The research method involves illustrating changes in skin tissue over time using high-frequency ultrasonography with a DUB SkinScanner device and a 22MHz probe. Measurements will be made before starting the study and then one month after each treatment. Patients are randomized by sequential numbers at each ultrasound measurement and randomly selected for examination by one of the researchers.

As a consequence of the ultrasound measurements, a series of acoustic density values will be obtained. These values, normalized to a color scale displaying the ultrasound image, will allow for a comparative analysis of changes in collagen and elastin fiber content in the dermis. The acoustic density value will be directly proportional to tissue density. The measurement will be conducted manually on the ultrasonographic image, averaging from a 2mm² rectangular area. The second observed parameter will be the skin thickness expressed in micrometers, comprising the epidermis and dermis thicknesses. The measurement will be manually performed on the ultrasonographic image, calculating the result as an average of three independent measurements in a specific area. Measurements will be taken before commencing the study and then one month after each treatment.

The second parameter planned to be observed is the thickness of the skin expressed in micrometers, as the sum of the thicknesses of the epidermis and dermis. The measurement will be performed manually on the ultrasonographic image, calculating the result as an average of three independent measurements in a given area. Measurements will be made before starting the study and then one month after each treatment. The aesthetic improvement of the treated area will be assessed a month after the third treatment by the subjects using the Global Aesthetic Improvement Scale (GAIS). The GAIS is a scale where 0 = worse, 1 = no change, 2 = improved, 3 = much improved, and 4 = very much improved. The subjects will also be asked to report their level of personal satisfaction with the treatment (very satisfied, satisfied, not satisfied) after completing the treatment and whether they would recommend the treatment to their friends (yes or no).

The aesthetic improvement of the treated area is assessed a month after the third treatment by the subjects using the Global Aesthetic Improvement Scale (GAIS). The GAIS is a scale where 0 = worse, 1 = no change, 2 = improved, 3 = much improved, and 4 = very much improved. The subjects are also asked to report their level of personal satisfaction with the treatment (very satisfied, satisfied, not satisfied) after completing the treatment.

Intervention Type
Procedure/Surgery

Primary outcome measure
The density of the skin measured using ultrasound before starting the study and then one month after each treatment

Secondary outcome measures

1. The thickness of the skin measured using ultrasonographic images before starting the study and then one month after each treatment
2. The aesthetic improvement of the treated area self-measured by the subjects using the Global Aesthetic Improvement Scale (GAIS) one month after the third treatment
3. The level of personal satisfaction with the treatment measured using a questionnaire after completing the treatment

Overall study start date
01/02/2019

Completion date
30/06/2021

Eligibility

Key inclusion criteria
1. Female volunteers
2. Aged between 30-60 years old
3. Seeking facial skin rejuvenation
4. Fitzpatrick skin types I to III and facial wrinkles classified as Glogau class II or higher

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
30 Years

Upper age limit
60 Years

Sex
Female

Target number of participants
20

Total final enrolment
20

Key exclusion criteria
1. Pregnancy or breastfeeding
2. Blood or platelet disorders
3. Facial surgery in the past year
4. Semi-permanent dermal fillers in the past year
5. Genetic conditions affecting fibroblasts or collagen
6. History of herpes simplex infection

7. Active skin diseases or infections in the treatment area
8. A tendency to develop hypertrophic scars or keloids
9. Immunosuppressive disorders or treatments
10. A history of skin cancer
11. Topical or oral tretinoin use
12. Undergone botulinum toxin and/or dermal filler injections, chemical peelings or laser treatments for facial rejuvenation in the past six months, or planned such treatments in the next six months

Date of first enrolment
01/10/2020

Date of final enrolment
30/10/2020

Locations

Countries of recruitment
Poland

Study participating centre
Małopolskie Centrum Biotechnologii UJ
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Sponsor information

Organisation
Innmedis

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Sponsor type
Industry

Website
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Funder(s)

Funder type
Industry

Funder Name
Innmedis

Results and Publications

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

Intention to publish date
30/01/2024

Individual participant data (IPD) sharing plan
The dataset generated during the study is available upon request from drlmajewska@gmail.com. Data comprising ultrasound values - skin density and skin thickness (patients marked by sequential numbers) will be shared for statistical analysis. All patients signed consent forms to participate in the study. There are no ethical or legal restrictions.

IPD sharing plan summary
Available on request, Published as a supplement to the results publication