Cairo University

Faculty of Dentistry

Research Ethics Committee

Microneedling with Platelet Rich Plasma Versus Microneedling Alone For Gingival Depigmentation: A Randomized Controlled Clinical Trial.

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Protocol Submitted for partial fulfillment of the master requirements in Faculty of Dentistry Cairo University

By

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(2019)

Code

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Human Subjects Application Form

Research title:
Microneedling with Platelet Rich Plasma Versus Microneedling Alone For Gingival Depigmentation: A Randomized Controlled Clinical Trial.

Full name of the researcher(s):
Abdelrahman Samir Abdullah sayed Ahmed

Affiliation of the researcher(s):
Category of study: Master [yes] PHD/D [ ] Others [ ]

Type of study design: Randomized clinical trial
Objective of the research: To evaluate the usage of microneedling with platelet rich plasma as a gingival depigmentation method in comparison to microneedling alone for pigment intensity reduction.

Steps of the research in short including the following:

- ***The inclusion and exclusion criteria for patient selection***.
  Inclusion criteria: *(Mostafa and Alotaibi 2022)*
  - *Patients exhibiting melanin hyperpigmentation in the anterior region of the upper or lower gingiva.*
  - ***Age ≥ 18 year old***.
  - *Patients should be free from any systemic diseases according to modified Cornell Medical index (Abramson 1966).*
  - *Non- smokers.*

  Exclusion criteria:*(Mostafa and Alotaibi 2022)*
  - *Fully edentulous patients.*
  - *Patients with endocrine disorders causing hyperpigmentation or drug induced gingival pigmentation. (Sreeja, Ramakrishnan et al. 2015)*
  - *Pregnant or lactating females.*

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11. Interventions

Pre-operative preparation phase includes ultrasonic scaling and oral hygiene instructions for all patients. Eligible patients will be randomly allocated into two groups.

***Clinical photographs**: Clinical photographs will be taken at baseline, 1 and 6 months postoperatively.*

- ***Intervention Group (Group A)**: Microneedling will be done with application of Platelet Rich Plasma for depigmentation.*
- ***Control Group (Group B)**: microneedling will be done alone for depigmentation.*

In both groups:

Local anesthesia (Articaine with 1:100,000 Epinephrine) will be administered by infiltration technique.

- *A Dermapen device will be used to microneedle the gingival tissue (model M8) with 24 microneedles arranged in rows, which is adjusted according to the gingival thickness at the 6th mode speed of 700 cycles/min(Mostafa and Alotaibi 2022).*
- *It will be laid perpendicular to gingival surface and MN will be carried out in horizontal, vertical and diagonal directions about four to five times for the whole hyperpigmented gingiva until mild microbleeding and mild erythema was clearly visible.*
- *Once bleeding points are observed on all areas of the pigmented gingiva, it will be irrigated using saline solution and dried using sterile gauze.*

Intervention group:

- *Patients receive injection of PRP in their Gingiva. To prepare PRP, 10mL of the patient's venous blood sample was taken manually with a sterile 10mL syringe and then centrifuged with 1800G/6min, buffy coat and plasma were then extracted and re-centrifuged with 2500G/15min. The injection of 1mL of PRP was immediately initiated*

with a 1 cc insulin syringe 30G, (0.1mL in each point of injection) (Iranmanesh, Rastaghi et al.).

Postoperative Care:

- *Patients were instructed to refrain from mechanical oral hygiene practices in regard to the target region for the day of the operation following each visit to minimize mechanical damage to the treated areas.*
- *If discomfort or itching was reported on the first day, analgesics were prescribed (Brufen 400 mg tablets, two times daily after meal).*
- *Restricted spicy, acidic, and coloring food. (Yussif, Abdel Rahman et al. 2019, Morsy 2022).*
- *Antiseptic mouth rinse 0,12% chlorhexidine rinse (Curasept, Curasept SpA, Saronno, Italy) were prescribed, for 60 seconds two times a day for 14 days (VAN SWAAIJ; VAN DER WEIJDEN; BAKKER; GRAZIANI et al., 2020).*
- *Apply an ice pack to the treated area for the first 24 hours (PIERI; ALDINI; FINI; MARCHETTI et al., 2012).*

- ***Mention the source of the patients enrolled in the research**.*
  Study is to be conducted in the Oral Medicine and Periodontology department, Faculty of Dentistry – Cairo University, Egypt.
  Patients are to be selected from the outpatient clinic of the department of Oral Medicine and Periodontology-Cairo University.
- *Sample size calculation.*
  We are planning a study of a continuous response variable from independent control and experimental subjects with (1) control per experimental subject. In a previous study the response within each subject group was normally distributed with standard deviation 0.444. if the true difference in the experimental and control means is 0.5, we will need to study 13 experimental subjects and 13 control subjects to be able to reject the null hypothesis that the population means of the experimental and control groups are equal with probability (power) 0.8. The type I error probability associated with this test of this null hypothesis is

0.05. To compensate for drop outs, 3 subjects will be added to each group to become 16 subjects, with a total of 32. Calculations were conducted using PS Power and Sample Size Calculations version 3.1.2. (Vanderbilt University, Nashville, Tennessee, USA).

- *Randomization in case of RCT.*
  The trial will be a parallel-group, two-arm, superiority, randomized controlled clinical trial with allocation ratio of 1:1.
  Patients will be randomly assigned to either test or control group using computer generated randomization (www.randomizer.org) which will be performed by the supervisor. The patients will be allocated to either test or control group

Direct benefit of the research to the human volunteer: Gingival depigmentation by minimally invasive method (microneedling with and without PRP).

The scientific interest and the desired public benefit of the research: to evaluate the microneedling with PRP efficacy as a gingival depigmentation method in comparison to other traditional methods for a 6 months follow up period.

Patient's full knowledge of the research steps: Reading [ ] Oral explanation [ ] Other [ ]

1. **I have carefully reviewed and understood the purpose of conducting the research and the nature of this study, and I understand what is necessary to accomplish these procedures.**
2. **The researcher has informed me of the possible therapeutic alternatives for this research.**
3. **The researcher has informed me of all the possible risks of this research and how to deal with it.**
4. **I agree to the imaging, recording, and all types of radiology to be performed in this study, on condition of anonymity.**
5. **I have made an accurate report on my health history and informed the doctor of all kinds of health reactions or unusual allergies to medicines, food, insect bites, anesthetics, dust or any reactions that have occurred to me from any other substances, abnormal bleeding or any other related conditions for my health.**
6. **I acknowledge that I am not involved in any other research from the beginning of this research until the end of this research and that I will inform the researcher if I enter any other research throughout the period of this research.**
7. **I undertake to return the medical devices (instruments) used in the research in case of discontinuation or when the research is completed.**

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After knowing the available information related to the research, the volunteer or the person in charge will be able to choose freely whether or not to subscribe. In case of approval, kindly fill out the data shown. The volunteer has the right to withdraw from the research without giving reasons anytime.

The researcher in charge of the research undertakes to keep the information of the volunteer person confidential by participating in the research, stating the methods used, such as replacing names with code numbers or hiding facial features when photographing (etc.).

Consent for Research Participation for Individuals Aged 21 Years or younger.

I, ..., National ID/....., Parent/Guardian of/....., here by consent to the above-mentioned treatment plan. I fully understand the treatment plan and its potential complications. All details of the treatment plan and follow-up sessions have been thoroughly explained to me.

Patient's Name: .....

Parent/Guardian's Name: .....

Phone Number: .....

..... :Date

Signature: Enji Ahmed **Abdelrahman Samir**

Date:

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