كلية طب الأسنان
لجنة أخلاقيات البحث العلمى(FDASU-REC)

ID: FDASU-RECD 1293 1123 1234.

Title: Effect of non-surgical periodontal therapy in hypertensive patients with assessment of Endocan and TNF-α levels in gingival crevicular fluid
(Case control study)

Date: 28/10/2024

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Informed Consent

Patient Name: ……..

Age:…….

Gender: …….

Address: ……

Mobile number: ……

Research title:

Effect of non-surgical periodontal therapy in hypertensive patients with assessment of Endocan and TNF-α levels in gingival crevicular fluid

(Case control study)

Aim of the study:

To investigate the correlation between the clinical parameters and the levels of Endocan and TNF-α in gingival crevicular fluid (GCF) before and after non-surgical periodontal therapy (NSPT) in stage II periodontitis patients with hypertension in comparison to non-hypertensive patients.

Research Location: Ainshams University

Number of participants: 40.

Participants selection: Random.

Inclusion criteria:

1. Patients with stage II periodontitis and controlled hypertension (self-reported history of a diagnosis of HTN by a physician and blood pressure (SBP < 140 and DBP < 90).
2. Both genders aged from 30-70.
3. Minimum 20 natural teeth excluding third molars.
4. Good compliance with the plaque control instructions following initial therapy.
5. Availability for follow-up and maintenance program.

Exclusion criteria:

1. Smokers.
2. Pregnant and lactating females.
3. Patients with other systemic diseases, such as diabetes mellitus, rheumatoid arthritis and cancer.

(According to Cornell Medical Index-Health Questionnaire).

4. Patients taking antibiotic, anti-inflammatory, and immunosuppressive therapy during the preceding 3 months before the start of the trial and during the study.
5. Patients who have undergone any periodontal therapy in the last 6 months.

Research steps:

1. Before enrollment, a detailed case history will be recorded.

2. A calibrated standard aneroid sphygmomanometer. The average of 3 blood pressure values (systolic blood pressure SBP and diastolic blood pressure DBP), will be taken at 1 minute interval, this will be used in data analyses.

(2020 International Society of Hypertension Global Hypertension Practice Guidelines) (25)

3. For all patients who are suitable for the study the following clinical evaluation parameters will be measured:

a) Plaque index (PI) (Silness&Löe, 1964)

b) Gingival index (GI) (Löe&Silness, 1963)
c) Probing depth (PD) (Caton, 1980).
d) Bleeding on probing (BOP) (Ainamo, 1985)
e) Clinical attachment level (CAL) (Ramfjord, 1967).
f) Standardized periapical radiograph. (Pananou, 2017)

Note: Full mouth assessment will be done and then the deepest site will be evaluated for the GCF sample.

4. Baseline GCF samples will be taken the day after patients were clinically evaluated to prevent contamination with blood related to the probing of inflamed areas.
5. The sample areas will be insulated with cotton rolls to prevent saliva contamination and all supragingival plaque will be eliminated. The paper strips will be placed into the periodontal pocket and then permitted to remain for 30s.
6. All patients will undergo full mouth NSPT, this will be done using ultrasonic and hand instruments.
7. The patients will receive oral hygiene instructions including tooth brushing using modified bass technique. All patients will be provided with toothbrush (soft), toothpaste (signal) and interdental cleaning with dental floss or interdental brush.
8. Two weeks follow-up to ensure that appropriate oral hygiene instructions are followed. The clinical parameter to be assessed will be PI and BOP, patients with PI 2 and BOP > 10% will be eliminated from the study.
9. Then clinical evaluation, collection of samples and measuring of SBP and DBP will be performed at 3 months after NSPT in both groups.

Expected number of visits:

2-3 visits.

Time of visits:

8am- 1pm

Participant Risks and side effects:

Slight pain after scaling and bleeding during scaling.

Participant Benefits:
Improvement in oral health after scaling and subsiding of gingival inflammation.

As well as receiving correct oral hygiene instructions to maintain oral health.

Research importance:
Establishing an evidence based correlation between hypertension and periodontitis in order to reach potential new treatments for both.

Expected Research expenses on Participants: Zero

Expected Research expenses on Researcher:
50-70 thousands LE

Researcher benefits:
Academic advancement in getting a masters degree as well as publishing results.

In case the participant refuses participating in this research:
He/she will be provided with NSPT.

Participant data confidentiality:

Completely confidential will only be seen by the main researcher and the research results will be shared with the participant.

Participants are allowed to **withdraw** from the research at any time without any consequences.

Researcher contact information:

Main Researcher: Dr. Lana Ashraf, 01009021417

Researcher supervisor: Professor Hala Abu el ela and Dr. Hadeel Gamal 01017767662

Ethics committee contact number:

Associate professor Mary Medhat 0122288635

After reading the above details I agree on the terms and participation in this research.

Name of participant: ……..
Signature:…….
Date:……..

Note:
-Participants can withdraw from research at any time.
-Participant will receive a copy of the informed consent.