The Effect of Synbiotic Tablet Usage on the Clinical and Biochemical Parameters in Smokers and Nonsmokers with Gingivitis: A Randomized Placebo-Controlled Clinical Trial

Document Date: February 27, 2018

Study Design

This study designed as a double-blind randomized placebo-controlled clinical trial.

Participants were primarily divided into two groups according to their smoking and non-smoking status. Then both groups in itself were randomly assigned again into two groups as test and control groups. Randomization was performed by one researcher that had never any role in participant's treatment and clinical measurement processes (E.O.E). Random selection was made in first person's participation by coin toss and then next participant was included into the other group according to previous participant's group. Four groups in this study are shown below:

- Smoker(+), test group(T) given synbiotic tablets; (**T(+)**)
- Smoker(+), control group(C) given placebo tablets; (**C(+)**)
- Non-smoker(-), test group(T) given synbiotic tablets; (**T(-)**)
- Non-smoker(-), control group(C) given placebo tablets; (**C(-)**)

In the screening phase, clinical measurements were carried out as an initial evaluation and in the next visit biochemical and microbiological samples were collected for baseline examination and all participants were received mechanical debridement procedure including tooth-polishing (rubber-cup and abrasive paste) and scaling by the help of ultrasonic devices §§ and periodontal hand pieces ||||| before the experimental period. On the day of periodontal treatment each subject was instructed to chew one test or placebo tablet that was given according to their groups, per day, during 30 days. Test and placebo tablets were prepared to have the same characteristics in terms of shape, color, taste and size. Commercially available Probiotic Chewable Tablets ¶¶ (Table 1) were used in the test group and a placebo tablet had been prepared to same company with similar content with the test tablets but does not contain microorganisms. Oral hygiene training with tooth brush and floss was given to all participants. They were also instructed not to take other probiotic products throughout the test period. Clinical parameters including PI (28) and GI (29) and GCF samples had been obtained from all subjects on days 0 (baseline), 30 (1st month), and 60 (2nd month).Patients' professional supragingival plaque control was made in the control session of 1st and 2nd month. Side effects were recorded by patients'

verbal statement. Patients' all measurements and treatments were made by a single researcher who doesn't know in which group participants were included (N.E.).

Biochemical Analysis

GCF samples were collected at baseline, 1st and 2nd months from contralateral upper or lower buccal region of canine or incisors having the most significant presence of inflammation and plaque accumulation. As once regions were determined at baseline, it wasn't changed in other evaluations. After removal of supragingival plaque from interproximal surfaces with sterile curettes, these surfaces were air-dried and isolated with cotton rolls before GCF collection. GCF samples were collected with paper strips [##]. Paper strips were inserted into the pockets until feeling a slight resistance and hold for 30 sec. Care had been taken to avoid any mechanical damage and strips were discarded when contaminated with blood samples. Strips were then transferred to the calibrated device of Periotron 8000[***]. GCF volume was recorded to a computer as µl. Total of 4 strips taken from each individual were placed into eppendorf tube and first stored at -20°C, then at -80ºC until the time of analysis. IL-6, IL-8, IL-10 levels of GCF were measured using commercial kits [†††] by using ELISA method. The standard test procedure according to the manufacturers' instructions was applied.