

Benchmark controlled evaluation of the effect of a cosmetic product in improving gums condition – in use test under dentist control

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Study synopsis

The study objective is to assess the efficacy of a cosmetic product (toothpaste) in improving the signs of gingivitis maintaining in comparison to regular toothpaste.

In order to reach this goal, a double-blind, randomized, parallel-group, placebo-controlled clinical study is planned to be performed on 60 (66 enrolled) healthy female and male subjects more than 18 years old, with grade II gingivitis enrolled according to the specific inclusion and non-inclusion criteria. The subjects will use the assigned product (experimental or regular toothpaste according to the randomization list) 2-3 times a day for 28 days. The efficacy will be evaluated by changes in gingival index, plaque index and bleeding on probing carried out before and after 24 hours, 48 hours, 7 days and 28 days of product use. The subjects will also give their opinion about subjective perception of the efficacy by means of questionnaire. The occurrence of adverse events will be also recorded. The study was approved by an independent ethics committee, and no protocol amendments were done after the approval and up to date.