

BiA 1 P-I

DUE TO BLINDING OF THE EXAMINER, RANDOMIZATION AND TREATMENT MUST BE PERFORMED BY A THERAPIST NOT DOING THE EXAMINATIONS.

Please remember that randomization will be performed after baseline measurements.

STUDY ALGORITHM (please follow CRF very carefully):

1. Screening and check inclusion and exclusion criteria. If OK Inform patient about study. Signe informed consent.
2. Put screened, but not included patients on excluded patient list.
3. Put patients that can be included and has accepted on the included patient list.
4. Percent plaque (6 surfaces/tooth).
5. BASELINE measurements by examiner.
6. RANDOMIZATION and TREATMENT BY THERAPIST OTHER THAN EXAMINER. Confer randomization list (write Labrida BioClean or control treatment in patient list and note sheet in journal).

NOW SCHEDULE THE FOLLOWING APPOINTMENTS:

7. Patient rescheduled with examiner at 4 weeks
8. Patient rescheduled with therapist at 3 months. PLEASE REMEMBER: TREATMENT ACCORDING TO RANDOMIZATION AT FIRST TREATMENT.
9. Patient rescheduled with examiner at 6 months.
10. Patient rescheduled with therapist at 6 months (IMPORTANT right after examination, can be same day or up to two weeks later). PLEASE REMEMBER: TREATMENT ACCORDING TO RANDOMIZATION AT FIRST TREATMENT.
11. Patient rescheduled with therapist at 9 months. PLEASE REMEMBER: TREATMENT ACCORDING TO RANDOMIZATION AT FIRST TREATMENT.
12. Patient rescheduled with examiner at 12 months.

IF QUESTIONS PLEASE CONTACT CASPAR WOHLFAHRT TEL +4747905629.

Blue = examiner

Red = therapist