

Study Protocol & Statistical Analysis Plan (SAP)

Official Title:

Comparative Assessment of Three-Dimensional Soft and Hard Tissue Changes Following Rapid Maxillary Expansion with Face Mask, Mini Maxillary Protractor, and Modified Splints, Elastics, and Chin Cup Protocols in Patients with Class III Malocclusion: A Prospective Randomized Controlled Clinical Trial

NCT Number:

(To be assigned after registration)

Document Date:

[21.02.2024]

Funding:

This study was supported by the Scientific Research Projects Coordination of Erciyes University (BAP, project number: ID-TDH 2024-13977)

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Study Protocol

Study Type and Design

Interventional, Randomized Controlled Clinical Trial

Allocation: Randomized

Intervention Model: Parallel Assignment

Masking: None (Open Label)

Primary Purpose: Treatment

Study Population

Growing patients with Class III skeletal malocclusion, aged 9–12 years.

Interventions

1. Rapid Maxillary Expansion with Face Mask (RME/FM)
2. Mini Maxillary Protractor (MMP)
3. Modified Splint with Elastics and Chin Cup (Modified SEC III)
4. Control Group (archival untreated Class III patients)

Primary Outcome Measures

Change in 3D soft tissue profile (facial convexity, mentolabial angle) from baseline to 9 months. Positional changes of anthropometric soft tissue landmarks.

Secondary Outcome Measures

Change in skeletal parameters (SNA, SNB, ANB, overjet, overbite) from baseline to 9 months. Dentoalveolar changes (incisor inclination, linear distances).

Study Dates

Start Date: February 21 2024

Primary Completion Date: January 09 2025

Study Completion Date: March 03 2025

Ethics

Approved by the Clinical Research Ethics Committee of Erciyes University (Approval No: 2024/44, Date: Jan 10, 2024). Approval also obtained from the Turkish Medicines and Medical Devices Agency (E-61749811-000-2961523, No: 2023-213).

Statistical Analysis Plan (SAP)

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Statistical Analysis Plan (SAP)

Software

SPSS Statistics version 21.0 (IBM Corp., Armonk, NY, USA).

Normality Testing

Shapiro–Wilk test used to evaluate distribution of continuous variables.

Between-Group Comparisons

Parametric variables: One-way ANOVA with post-hoc Tukey's tests.

Non-parametric variables: Kruskal–Wallis test with post-hoc Dunn's or Durbin–Conover tests.

Within-Group Comparisons (T0 vs T1)

Parametric: Paired samples t-test.

Non-parametric: Wilcoxon signed-rank test.

Sex-Based Comparisons

Independent samples t-test for parametric variables.

Mann–Whitney U test for non-parametric variables.

Reliability Testing

Intra-examiner reproducibility assessed by repeating 10 randomly selected cases at 1-month interval.

Reliability calculated using Intraclass Correlation Coefficient (ICC) and Cronbach's alpha.

Level of Significance

A p-value of <0.05 considered statistically significant.