Informed Consent Form (ICF)

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)

Principal Investigator:
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Sub-Investigator:
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Department of Orthodontics, Faculty of Dentistry
Erciyes University, Kayseri, Turkey

Informed Consent Form (Group with Rapid Maxillary Expansion and Face Mask)

Participant Information

Full Name, Address: .....
Protocol No. and Tel. No. (if applicable): .....

Information

This clinical study is a research project. Our aim is to correct the discrepancy between the jaws in volunteers with retrusive maxilla and/or protrusive mandible by advancing the maxilla and teeth forward. For this purpose, a rapid maxillary expansion (RME) appliance will be applied to the upper jaw. Elastics will be attached between the face mask (supported from the forehead and chin) and the RME appliance, and their effects on forward movement of the maxilla will be evaluated. After obtaining informed consent from the patients and/or their legal guardians, the study entitled 'Comparison of the Effects of Different Maxillary Protraction Methods Using Cephalometry and 3D Stereophotogrammetry' will be conducted.

Your child has been selected for this study because he/she is between 9–12 years old and has a retrusive maxilla and/or protrusive mandible.

Participation in this research is voluntary. In this study, 45 volunteers like your child will be treated.

In this group, 15 patients will receive a rapid maxillary expansion appliance followed by a face mask with elastics. The effects of this mechanics on the maxilla, mandible, teeth, and soft tissues will be evaluated. Each patient will be given a tooth- and tissue-borne maxillary expander that covers the upper posterior teeth and palate with an expansion screw. The screw will be turned twice daily. After one week, elastics will be placed between the hooks of the expander and the face mask to apply orthopedic forces. Treatment success depends on full compliance. Elastics must be worn approximately 16 hours per day; otherwise, the treatment will not be successful. The use of elastics will continue until the intermaxillary relationship is corrected (average 6–9 months).

During treatment, mild redness may occur on the gums. This can be eliminated by carefully cleaning the appliance margins with toothbrushing. Mild pain or redness may occur in the areas where the face mask contacts the forehead and chin. Other significant side effects are very rare.

This study will be conducted with 3 groups of 15 patients each.

Volunteers who agree to participate (or their legal guardians) are responsible for attending appointments on the scheduled dates, complying fully with treatment, and following the

oral hygiene instructions provided.

If the volunteer cannot be contacted or misses appointments, participation in the study will be terminated.

The Ethics Committee, monitors, inspectors, the Ministry of Health, and relevant health authorities will have direct access to the participant's original medical records, but confidentiality will be maintained. By signing this ICF, the volunteer or legal guardian consents to such access.

If new information emerges during the research that may affect the volunteer's willingness to continue participation, the volunteer or legal guardian will be informed promptly.

If there is no expected clinical benefit for the volunteer, this will be disclosed.

Prior to participation, the volunteer or legal guardian must sign this document indicating willingness to participate.

Participation is entirely voluntary. You may initially consent and later withdraw without giving any reason. This will not affect the medical care you or your child receives.

In accordance with legal requirements, all records identifying the volunteer will be kept confidential, even in the event of publication.

For any questions or clarification, you may directly contact Research Assistant Tuba Ünlü Çiftçi (Erciyes University, Faculty of Dentistry, Department of Orthodontics) at +90 554 508 71 96.

The Faculty Ethics Committee has approved this study in accordance with the Declaration of Helsinki, confirming that it complies with ethical, moral, and medical standards.

Consent of the Volunteer

I have read all the explanations in the Informed Consent Form. I have received written and verbal explanations about the purpose and content of the study from Assoc. Prof. Dr. Gökhan Çoban and Research Assistant Dr. Tuba Ünlü Çiftçi. I understand that I am free to participate voluntarily, that I may withdraw from the study at any time without justification, and that I may also be withdrawn from the study at the discretion of the investigator.

"I voluntarily agree to participate in this research study without any pressure or coercion."

Volunteer/Legal Guardian
Name, Surname: .....

Signature: .....
Date: .....

Researcher Providing the Information
Name, Surname: .....
Signature: .....
Date: .....

Witness
Name, Surname: .....
Signature: .....
Date: .....

Note: For minors under guardianship, the consent of the parent or legal guardian must be obtained.

Informed Consent Form (ICF)

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

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Sub-Investigator:
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Department of Orthodontics, Faculty of Dentistry
Erciyes University, Kayseri, Turkey

Informed Consent Form (Group with Mini Maxillary Protractor)

Participant Information

Full Name, Address: .....
Protocol No. and Tel. No. (if applicable): .....

Information

This clinical study is a research project. Our aim is to correct the discrepancy between the jaws in volunteers with retrusive maxilla and/or protrusive mandible by advancing the maxilla and teeth forward. For this purpose, a mini maxillary protractor (MMP) will be applied in combination with rapid maxillary expansion (RME) mechanics. Elastics will be attached between the maxillary splint and the mandibular appliance, and their effects on forward movement of the maxilla will be evaluated.

Your child has been selected for this study because he/she is between 9–12 years old and has a retrusive maxilla and/or protrusive mandible.

Participation in this research is voluntary. In this study, 45 volunteers like your child will be treated.

In this group, 15 patients will receive a mini maxillary protractor (MMP). The effects of this mechanics on the maxilla, mandible, teeth, and soft tissues will be evaluated. Each patient will be given an acrylic splint covering the occlusal, buccal, and lingual surfaces of the mandibular posterior teeth, connected to a modified intraoral component adapted from a Petit-type face mask. Elastics will be placed to apply orthopedic forces. Treatment success depends on full compliance. Elastics must be worn approximately 16 hours per day; otherwise, the treatment will not be successful. The use of elastics will continue until the intermaxillary relationship is corrected (average 6–9 months).

During treatment, mild redness may occur on the gums. This can be eliminated by carefully cleaning the appliance margins with toothbrushing. Mild pain or redness may occur in the areas where the appliance contacts the oral tissues or the chin. Other significant side effects are very rare.

This study will be conducted with 3 groups of 15 patients each.

Volunteers who agree to participate (or their legal guardians) are responsible for attending appointments on the scheduled dates, complying fully with treatment, and following the oral hygiene instructions provided.

If the volunteer cannot be contacted or misses appointments, participation in the study will be terminated.

The Ethics Committee, monitors, inspectors, the Ministry of Health, and relevant health authorities will have direct access to the participant's original medical records, but confidentiality will be maintained. By signing this ICF, the volunteer or legal guardian consents to such access.

If new information emerges during the research that may affect the volunteer's willingness to continue participation, the volunteer or legal guardian will be informed promptly.

If there is no expected clinical benefit for the volunteer, this will be disclosed.

Prior to participation, the volunteer or legal guardian must sign this document indicating willingness to participate.

Participation is entirely voluntary. You may initially consent and later withdraw without giving any reason. This will not affect the medical care you or your child receives.

In accordance with legal requirements, all records identifying the volunteer will be kept confidential, even in the event of publication.

For any questions or clarification, you may directly contact Research Assistant Tuba Ünlü Çiftçi (Erciyes University, Faculty of Dentistry, Department of Orthodontics) at +90 554 508 71 96.

The Faculty Ethics Committee has approved this study in accordance with the Declaration of Helsinki, confirming that it complies with ethical, moral, and medical standards.

Consent of the Volunteer

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"I voluntarily agree to participate in this research study without any pressure or coercion."

Volunteer/Legal Guardian
Name, Surname: .....
Signature: .....
Date: .....

Researcher Providing the Information
Name, Surname: .....

Signature: .....
Date: .....

Witness
Name, Surname: .....
Signature: .....
Date: .....

Note: For minors under guardianship, the consent of the parent or legal guardian must be obtained.

Informed Consent Form (ICF)

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

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Sub-Investigator:
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Department of Orthodontics, Faculty of Dentistry
Erciyes University, Kayseri, Turkey

Informed Consent Form (Group with Modified SEC III Protocol)

Participant Information

Full Name, Address: .....
Protocol No. and Tel. No. (if applicable): .....

Information

This clinical study is a research project. Our aim is to correct the discrepancy between the jaws in volunteers with retrusive maxilla and/or protrusive mandible by advancing the maxilla and controlling the mandible. For this purpose, a Modified SEC III appliance will be applied, which combines a splint, intermaxillary elastics, and a chin cup. The effects of this treatment on the maxilla, mandible, teeth, and soft tissues will be evaluated.

Your child has been selected for this study because he/she is between 9–12 years old and has a retrusive maxilla and/or protrusive mandible.

Participation in this research is voluntary. In this study, 45 volunteers like your child will be treated.

In this group, 15 patients will receive a Modified SEC III appliance. The effects of this mechanics on the jaws, teeth, and soft tissues will be evaluated. Each patient will be given a full-coverage mandibular splint combined with hooks for intermaxillary elastics and an occipital chin cup to apply orthopedic forces. Treatment success depends on full compliance. Elastics must be worn approximately 16 hours per day; otherwise, the treatment will not be successful. The use of elastics will continue until the intermaxillary relationship is corrected (average 6–9 months).

During treatment, mild redness may occur on the gums. This can be eliminated by carefully cleaning the appliance margins with toothbrushing. Mild pain or redness may occur in the areas where the chin cup contacts the skin. Other significant side effects are very rare.

This study will be conducted with 3 groups of 15 patients each.

Volunteers who agree to participate (or their legal guardians) are responsible for attending appointments on the scheduled dates, complying fully with treatment, and following the oral hygiene instructions provided.

If the volunteer cannot be contacted or misses appointments, participation in the study will be terminated.

The Ethics Committee, monitors, inspectors, the Ministry of Health, and relevant health authorities will have direct access to the participant's original medical records, but confidentiality will be maintained. By signing this ICF, the volunteer or legal guardian

consents to such access.

If new information emerges during the research that may affect the volunteer's willingness to continue participation, the volunteer or legal guardian will be informed promptly.

If there is no expected clinical benefit for the volunteer, this will be disclosed.

Prior to participation, the volunteer or legal guardian must sign this document indicating willingness to participate.

Participation is entirely voluntary. You may initially consent and later withdraw without giving any reason. This will not affect the medical care you or your child receives.

In accordance with legal requirements, all records identifying the volunteer will be kept confidential, even in the event of publication.

For any questions or clarification, you may directly contact Research Assistant Tuba Ünlü Çiftçi (Erciyes University, Faculty of Dentistry, Department of Orthodontics) at +90 554 508 71 96.

The Faculty Ethics Committee has approved this study in accordance with the Declaration of Helsinki, confirming that it complies with ethical, moral, and medical standards.

Consent of the Volunteer

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Volunteer/Legal Guardian
Name, Surname: .....
Signature: .....
Date: .....

Researcher Providing the Information
Name, Surname: .....
Signature: .....
Date: .....

Witness
Name, Surname: .....
Signature: .....
Date: .....

Note: For minors under guardianship, the consent of the parent or legal guardian must be obtained.