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Effects of different functional therapy protocols on airway dimensions during Herbst appliance therapy

Submission date
08/11/2018

Recruitment status
No longer recruiting

Registration date
06/12/2018

Overall study status
Completed

Last Edited
26/10/2020

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The position of the lower jaw can influence the position of the hyoid bone and the tongue, which can then affect the dimensions of the airway. Lower jaw advancement is a type of surgery that moves the jaw, and can change the dimensions of the airway. A Herbst appliance is a device that is attached inside the mouth to move the jaw. The jaw can be moved in a single step (maximum advancement) or in smaller, multiple steps (incremental advancement) using a Herbst appliance. This study aims to look at the effects of maximum and incremental advancement using a Herbst appliance on airway dimensions and position of the hyoid bone in young adults with a retruded lower jaw.

Who can participate?
Patients aged 14-18 with mandibular retrognathia

What does the study involve?
Participants will be randomly allocated to one of two groups. One group will receive maximum advancement (MA), whereas the other will receive incremental advancement (IA). Both groups will receive mandibular advancement treatment using the Herbst-RPE appliance. The MA group will receive treatment for approximately 9-10 months. The IA group will receive treatment every 2 months until the treatment is complete.

What are the possible benefits and risks of participating?
The possible benefit of participating in this study is that patients will receive treatment more quickly, as they will not have to wait to be treated. There are no known risks to participants taking part in this study.

Where is the study run from?
Erciyes University, Faculty of Dentistry, Department of Orthodontics, Kayseri (Turkey)

When is the study starting and how long is it expected to run for?
November 2011 to September 2017

Who is funding the study?
This study does not require funding as all treatments are standard orthodontic treatments performed by Erciyes University

Who is the main contact?
Nisa Gul Amuk
nisagul@erciyes.edu.tr

Contact information

Type(s)
Scientific

Contact name
Dr Nisa Gul Amuk

ORCID ID
http://orcid.org/0000-0002-3752-7100

Contact details
Erciyes Üniversitesi diş Hekimliği Fakültesi Ortodonti Anabilim Dalı
Kayseri
Türkiye
38039
+905309237573
nisa.gul86@hotmail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2011/107

Study information

Scientific Title
Changes in pharyngeal airway dimensions following incremental and maximum bite advancement during Herbst appliance therapy in young adult patients: a randomized prospective clinical study

Study objectives
Null hypothesis:
There is no difference between maximum bite advancement and ıncremental advancement with Herbst appliance therapy on pharyngeal airway dimensions and hyoid bone position.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Erciyes University Clinical Trials Ethical Committee, 06/12/2011, 2011/107

Study design
Interventional prospective single-center double-blinded randomised controlled parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Skeletal class II malocclusion with mandibular retrognathy

Interventions
Participants will be randomly allocated to receive either maximum advancement or incremental advancement in a 1:1 ratio using a random number table.
Both groups will receive mandibular advancement using the Herbst-RPE appliance with a stainless steel casted splint design.For the group receiving maximum advancement, advancement will be adjusted until a tet-a-tet incisor relation or super class I molar relationship is obtained. This will be completed for approximately 9-10 months. For the group receiving incremental advancement, a 2 mm shim will be inserted to the pivot ends of the plungers after a 4-5 mm initial forward movement of the mandible. For this group, advancement steps will continue every 2 months until a tet-a-tet incisor relation or super class I molar relationship is obtained.

Intervention Type
Device

Primary outcome measure
Changes in pharyngeal airway and hyoid position, assessed using lateral cephalometric radiography before using the Herbst-RPE appliance and immediately after appliance removal

Secondary outcome measures
Skeletal changes, assessed using lateral cephalometric radiography before using the Herbst-RPE appliance and immediately after appliance removal

Overall study start date
28/11/2011

Completion date
05/09/2017

Eligibility

Key inclusion criteria
1. Skeletal Class II malocclusion (ANB angle >4°) and mandibular retrognathy (SNB <78°)
2. Bilateral Class II molar and canine relationship (at least 3.5 mm)
3. Increased overjet (more than 7 mm)
4. Normal or decreased vertical dimensions (SN-GoGn ≤32)
5. Minimal crowding (≤4) and no missing teeth on upper and lower arches
6. Aged 14-18 years

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
50

Total final enrolment
48

Key exclusion criteria
1. Craniofacial anomalies
2. Musculoskeletal diseases
3. Severe facial asymmetry
4. Severe maxillary transverse deficiency
5. Poor oral hygiene

Date of first enrolment
01/10/2014

Date of final enrolment
01/10/2015

Locations

Countries of recruitment
Türkiye

Study participating centre
Erciyes University, Faculty of Dentistry, Department of Orthodontics
Kayseri
Türkiye
38039

Sponsor information

Organisation
Erciyes University Clinical Trials Ethical Committee

Sponsor details
Erciyes Üniversitesi Merkez Kampüs Tıp Fakültesi Dekanlığı 38039 Talas Yolu Melikgazi/KAYSERİ, TURKEY
Melikgazi/Kayseri
Türkiye
38039
+90 0 352 437 49 10 - 11
tipdekanlik@erciyes.edu.tr

Sponsor type
University/education

ROR
https://ror.org/047g8vk19

Funder(s)

Funder type
Other

Funder Name
No funding

Results and Publications

Publication and dissemination plan
We are intending publish this manuscript as original article in an peer-reviewed journal in June 2019

Intention to publish date

05/06/2019

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	24/05/2019	26/10/2020	Yes	No