

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

<b>Submission date</b> 08/11/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 06/12/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/10/2020	<b>Condition category</b> Oral Health	<input type="checkbox"/> 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 incremental 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 retrognathia

**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  $>4^{\circ}$ ) and mandibular retrognathia (SNB  $<78^{\circ}$ )
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  $\leq 32$ )
5. Minimal crowding ( $\leq 4$ ) 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?
<a href="#">Results article</a>	results	24/05/2019	26/10/2020	Yes	No