

PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Long-term stability after Class II treatment with the Herbst appliance

Trial Acronym

Long-term stability Herbst treatment

URL of the trial

[---]*

Brief Summary in Lay Language

The aim of this study is to investigate the long-term stability of results obtained by Herbst appliance treatment. Therefore, the post-treatment changes of the masticatory system are to be investigated.

The Herbst appliance is a fixed functional orthodontic appliance causing permanent mandibular advancement which results in adaptation of the temporomandibular joint as well as the alveolar processes and therefore corrects mandibular retrusion and the respective Class II relation.

Individuals who received Herbst appliance treatment as well as subsequent multibracket appliance treatment at the Department of Orthodontics, University of Giessen are eligible to participate, if treatment with these appliances was completed at least 15 years ago.

In case of participation in this study, the current orthodontic diagnosis will be documented taking impressions of the upper and lower jaw. Furthermore, general oral health will be assessed by clinical inspection of oral mucosa and dental status. In addition, the temporomandibular joints and the masticatory muscles are to be assessed clinically as well as lower jaw mobility using a caliper. Finally, the facial profile will be recorded taking photographs.

Brief Summary in Scientific Language

To evaluate long-term stability after orthodontic (Class II) treatment with the Herbst appliance, dental and dentofacial changes which occurred during a post-treatment period of 15 years are to be analysed. Therefore, patients who received treatment at the Department of Orthodontics, University of Giessen which was completed at least 15 years ago, will be assessed in a clinical, non-interventional trial. The generated post-treatment data will be compared (as far as possible) to an untreated control group (Class I) of similar age.

Stability of sagittal and vertical incisor relationship, sagittal molar and canine relationship as well as changes of the facial profile, the current orthodontic



diagnosis (PAR-Index), general oral health and temporomandibular joint function are to be assessed.

Organizational Data

- DRKS-ID: **DRKS00006354**
- Date of Registration in DRKS: **2014/07/21**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **146/13 , Ethik-Kommission des Fachbereichs Medizin der Justus-Liebig-Universität Gießen**

Secondary IDs

Health condition or Problem studied

- Free text: **Class II malocclusion (stability after treatment)**
- ICD10: **K07 - Dentofacial anomalies [including malocclusion]**

Interventions/Observational Groups

- Arm 1: **(after) Herbst treatment; taking impressions to obtain study models, inspection of oral cavity, screening of temporomandibular joint and lower jaw mobility, taking photographs**
- Arm 2: **Class I occlusion (untreated); evaluation of orthodontic study models, no clinical assessment**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Non-randomized controlled trial**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Historical**
- Purpose: **Prognosis**
- Assignment: **Parallel**
-

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Control: **Historical**

Purpose: **Prognosis**

Assignment: **Parallel**

Phase: **N/A**

- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Stability of overjet during the post-treatment observation period; changes > 1 millimeter compared to the control group are to be considered as clinically relevant (measurements performed on orthodontic study models).

Secondary Outcome

Changes of overbite, sagittal molar- and canine relationship (assessment using orthodontic study models from before treatment, after treatment and after the post-treatment period);

Changes of facial profile (assessment from photographs from before treatment, after treatment and after the post-treatment period);

Evaluation of orthodontic diagnosis (PAR-Index) using orthodontic study models from before treatment, after treatment and after the post-treatment period);

Evaluation of general oral health and temporomandibular joint function as well as the current orthodontic treatment need by means of clinical inspection

Countries of recruitment

- **DE Germany**

Locations of Recruitment

- University Medical Center **Poliklinik für Kieferorthopädie, Giessen**



Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/04/15**
- Target Sample Size: **32**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **no minimum age**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Herbst patients: Orthodontic Herbst appliance treatment as well as subsequent multibracket appliance treatment, treatment completed at least 15 years ago, pre-treatment overjet \geq 6mm and Class II molar relationship \geq 0,5 cusp widths (bilaterally) / 1,0 cusp widths (unilaterally)

Control group: Class I occlusion, no orthodontic treatment, observation period of at least 15 years (documentation by orthodontic study models)

Exclusion criteria

Failure of inclusion criteria, incomplete treatment records

Addresses

■ Primary Sponsor

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■ Contact for Scientific Queries

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Sources of Monetary or Material Support

■ Private sponsorship (foundations, study societies, etc.)

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■ **Institutional budget, no external funding (budget of sponsor/PI)**

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2015/07/02**

Trial Publications, Results and other documents

- Paper **Eur J Orthod. 2017 Jul 11. doi: 10.1093/ejo/cjx051**
- Paper **Eur J Orthod. 2017 Dec 9. doi:10.1093/ejo/cjx091**
- Paper **J Orofac Orthop 2018 Feb 20 doi.org/10.1007/s00056-018-0125-5**

* This entry means the parameter is not applicable or has not been set.

*** This entry means that data is not displayed due to insufficient data privacy clearing.