Trial Description

Title
The effect of a bimaxillary occlusion splint (dynamic dental splint system Stressbite®) on postural control and balance in patients with bruxism.

Trial Acronym
[---]*

URL of the trial
[---]*

Brief Summary in Lay Language
[---]*

Brief Summary in Scientific Language
This study raises the question of the direct effect of a bimaxillary occlusion splint (dynamic dental splint system Stressbite®) on the standing equilibrium of patients with bruxism and whether reprogramming processes in the musculoskeletal system occur with increasing wearing time. The study hypothesis is that wearing the bimaxillary occlusal splint (hereinafter referred to as the occlusal splint) will have a direct influence on and improve the standing balance and that the standing balance will improve with increasing wearing time, even without wearing the occlusal splint (reprogramming). The aim of the study is to quantifiably investigate the influence of the occlusion splint on the posture and balance. If effects can be demonstrated, this would indicate that the occlusal splint has a reprogramming effect on the musculoskeletal system that can be used for therapeutic purposes. Follow-up studies could deal with the effect of further specific symptoms caused by craniomandibular dysfunctions (CMD). Furthermore, interdisciplinary therapy approaches and recommendations could result.

Do you plan to share individual participant data with other researchers?
Yes

Description IPD sharing plan
The statistical evaluations and the study protocol are made available. These can be requested from the study director by e-mail. All data will be passed on anonymously so that no conclusions can be drawn about the study participants.
**Secondary IDs**

**Health condition or Problem studied**

- Free text: ÜBERSETZUNG ERGÄNZEN

**Interventions/Observational Groups**

- Arm 1: ÜBERSETZUNG ERGÄNZEN

**Characteristics**

- Study Type: Interventional
- Study Type Non-Interventional: [---]*
- Allocation: Single arm study
- Blinding: [---]*
- Who is blinded: [---]*
- Control: Uncontrolled/Single arm
- Purpose: Treatment
- Assignment: Single (group)
- Phase: II
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): N/A

**Primary Outcome**

ÜBERSETZUNG ERGÄNZEN

**Secondary Outcome**
Countries of recruitment

- CH Switzerland

Locations of Recruitment

- Doctor's Practice Basel

Recruitment

- Planned/Actual: Actual
- (Anticipated or Actual) Date of First Enrollment: 2019/12/04
- Target Sample Size: 20
- Monocenter/Multicenter trial: Monocenter trial
- National/International: National

Inclusion Criteria

- Gender: Both, male and female
- Minimum Age: 20 Years
- Maximum Age: 40 Years

Additional Inclusion Criteria

Patients with bruxism between the ages of 20 and 40,
good knowledge of German,
informed consent

Exclusion criteria

Braces (fixed or loose), splint or artificial teeth;
rheumatic diseases or arthrosis;
Fractures/surgery of the jaw, skull bones or cervical spine (less than 12 months ago);
Herniated disc of the cervical spine (less than 12 months ago);
acute toothache/inflammation of the oral cavity;
neoplasia/tumour diseases;
depressions;
neurological diseases, with influence on the sense of balance;
subjects with pain in the joints of the lower extremity;
previous operations on hip, knee and ankle joints;
inner ear problems/ vertigo/head injuries in the past; Pregnancy

Translated with www.DeepL.com/Translator (free version)

Addresses

■ Primary Sponsor

Zahnarztpraxis Schifflände und Privatinstutit CMD
Mr. M.Sc. Implantologie Kian Dilmaghani
Eisengasse12 / Tanzgässlein 2
4051 Basel
Switzerland
Telephone: +41 61 261 35 45
Fax: [---]*
E-mail: praxis at dilmaghani.ch
URL: [---]*

■ Contact for Scientific Queries

alphaclinic Zürich
Mr. PD Dr.med. Patrick Vavken
Kraftstrasse 29
8044 Zürich
Switzerland
Telephone: +41 44 388 84 11
Fax: +41 44 388 84 21
E-mail: vavken at alphaclinic.ch
URL: [---]*

■ Contact for Public Queries

ZHAW Gesundheit Masterstudiengang Physiotherapie
Mr. B.Sc. Physiotherapie Marc Kwidzinski
Technikumstrasse 71
8400 Winterthur
Switzerland
Telephone: +41 787511722
Fax: [---]*
E-mail: kwidzmar at students.zhaw.ch
URL: [---]*

Sources of Monetary or Material Support

■ Private sponsorship (foundations, study societies, etc.)
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Zahnarztpraxis Schifflände und Privatinstutitute CMD
Mr. M.Sc. Implantologie Kian Dilmaghani
Eisengasse12 / Tanzgässlein 2
4051 Basel
Switzerland

Telephone: 061 261 35 45
Fax: [---]*
E-mail: praxis at dilmaghani.ch
URL: [---]*

Status

- Recruitment Status: Recruiting complete, follow-up complete
- Study Closing (LPLV): 2020/04/20

Trial Publications, Results and other documents

- Approval of ethics comm. (mandatory for transfer to Studybox) Ethikvotum

* 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.