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Effects on sleep bruxism activity of two different removable oral appliances detected with nocturnal instrumental recordings

Submission date
03/02/2017

Recruitment status
No longer recruiting

Registration date
09/03/2017

Overall study status
Completed

Last Edited
09/07/2024

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Bruxism is a repetitive jaw-muscle activity that causes teeth to clench and grind. Bruxism can occur during sleep (sleep bruxism (SB)) or when patients are awake (awake bruxism (AB)). SB can disrupted sleep, wear out teeth and can ruin dental work. SB can be managed by using oral appliances (OAs). OAs are small mouth guards worn at night that are designed to prevent clenching of teeth and keeps the teeth separated. The main type of OA that is used is the occlusal splint which is a standard mouth guard. However, there are other options of OA that could work to improve SB such as a functional appliance which is more like a retainer with a button that sits on the roof of the mouth and stainless steel that goes around certain teeth. There is a need to find out how to best manage SB. The aim of this study is to see which oral appliance is able better at reducing SB and improving its painful effects.

Who can participate?
Adults suffering from sleep bruxism.

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in the first group are treated using occlusal splint appliance. This is a small mouth guard that separates the teeth. Participants in the second group are treated using functional appliance which is a type of dental retainer. Participants in both groups are instructed to wear their appliance every night for 12 months. Participants are followed up after one, three, six and 12 months with night-time recordings of their teeth movement to detect changes in sleep bruxism activity.

What are the possible benefits and risks of participating?
Participants may benefit from being protected against the impacts of sleep bruxism (i.e. tooth wear, dental fractures and dental sensitivity). There are no notable risks involved with participating.

Where is the study run from?
Dental School, University of Torino (Italy)

When is the study starting and how long is it expected to run for?
October 2014 to October 2016

Who is funding the study?
University of Torino (Italy)

Who is the main contact?
Dr. Andrea Deregibus
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
bitebruxism2016

Study information

Scientific Title
Effects on sleep bruxism activity of functional appliances and occlusal splints detected with nocturnal instrumental ECG/EMG recording: A randomized clinical trial

Study objectives
The aim of this study is to find out if sleep bruxism activity is influenced by the use of two different oral appliances: occlusal splints and functional appliances.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee A.O.U Città della Salute e Della Scienza di Torino, 15/09/2016, ref: 0089207

Study design

Single-centre randomized interventional trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Sleep bruxism

Interventions
Participants are randomly allocated to one of two groups using a random number list software generator.

Group 1: Occlusal splint group (OS)
Participants in this group are treated with an occlusal splint appliance (Michigan bite plane) which is a standard acrylic plate. This is worn in the mouth every night for 12 months as per the normal standard of care.

Group 2: Functional appliance group (FA)
Participants in this group are treated with a functional orthopedic appliance. This consists of a palatal button made of acrylic resin and three bites (one anterior and two posteriors) made of resilient stainless steel. This is worn in the mouth every night for 12 months.

Participants in both groups are recorded with multiple nocturnal instrumental electrocardiogram /electromyograms (ECG/EMG) in order to screen and control possible variation in sleep bruxism activity. The participants are given a nighttime recording device and are trained on how to use it and where to put the electrodes. They are provided with written instructions and a night-time telephone number to call in the event of difficulties. The ECG/EMG recordings are conducted with a three channels validate portable device for sleep bruxism diagnosis (Bruxoff ®, OT Bioelettronica, Torino, Italy). Two channels are used to acquire surface electromyography (sEMG) bilaterally from the masseter muscle, and the third channel is used to acquire the electrocardiographic activity (ECG). The three signals are sampled at 800 Hz, with 8 bit resolution. The data is stored on a MicroSD card as a binary file. The sEMG channels are filtered between 10 and 400 Hz with gain 4300. The electrocardiographic (ECG) channel is filtered between 15 and 160 Hz with gain 700. Surface EMGs from the masseter muscle of both sides are detected with disposable bipolar concentric electrodes (Code®, Spes Medica, Battipaglia, Italy), with a radius of 16 mm and with detection site made of AgCl. The heart frequency is detected with a disposable bipolar electrode located on the left side of the thorax just below the pectoral muscles.

At the beginning of the ECG/EMG recording, the participants are asked to perform three maximum voluntary clenching (MVC) lasting 3 seconds each and separated by 10 seconds of rest. The greatest of the MVC measures are used for normalizing the EMG values as a percent of MVC. Scoring on the Bruxoff recordings is automatically performed by dedicated software (Bruxmeter ®, OT Biolettonica, Torino, Italy). The software is able to classify a SB episode if the sEMG burst is greater than 10% MVC and if it immediately follows (1-5 seconds interval) a heart rate increase of 20% with respect to the baseline. Instrumental evaluation allows to identify specific sEMG signals: tonic, phasic and mixed.

The total duration of the treatment and follow-up is 24 months.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Occlusal splint appliance (Michigan bite plane), functional orthopedic appliance

Primary outcome(s)
Sleep bruxism index is measured using the Bruxmeter software at baseline, 1, 3, 6, and 12 months.

Key secondary outcome(s))
Identification of variations in sleep bruxism index and/or in specific EMG signals (tonic, phasic or mixed) measured using from Bruxmeter software at baseline, 1, 3, 6, and 12 months.

Completion date
20/10/2016

Eligibility

Key inclusion criteria
1. Able to give informed consent
2. Suffering from sleep bruxism
3. Good oral hygiene and periodantal status
4. No extended dental restorations

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
40

Key exclusion criteria
1. Neurological diseases
2. Signs/symptoms of tempormandibular disorders

3. Already wearing occlusal splints
4. Post traumatic patients
5. Suffering from other sleep disorders (i.e. sleep apnea, restless leg syndrome)

Date of first enrolment
01/05/2014

Date of final enrolment
20/04/2015

Locations

Countries of recruitment
Italy

Study participating centre
Dental School, Department of Orthodontics
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Sponsor information

Organisation
University of Torino

ROR
https://ror.org/048tbm396

Funder(s)

Funder type
Not defined

Funder Name
Università degli Studi di Torino

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Andrea Deregibus at andrea.deregibus@unito.it

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		29/01/2024	09/07/2024	Yes	No