

Effects on sleep bruxism activity of clear aligners detected with nocturnal instrumental recordings

Submission date 03/02/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/03/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 09/03/2017	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Sleep bruxism is the medical term for grinding the teeth and clenching the jaw during sleep. It is associated with a number of clinical problems, including pain, tooth wear and failure of dental restorations. Some of these patients require orthodontic treatment. The use of clear aligners ("invisible braces") has increased in orthodontic practice. They are comparable to occlusal splints, plastic appliances that fit onto the teeth which are routinely used in patients suffering from sleep bruxism to prevent tooth wear. The aim of this study is to find out whether clear aligners can be used to treat sleep bruxism.

Who can participate?

Adolescents (aged from 16 years) and adults (>18 years) requiring orthodontic treatment and 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 orthodontic clear aligners. Participants in the second group are treated using a palatal splint with no tooth coverage. For participants in both groups,, sleep bruxism activity is recorded at home in the night at the start of the study and then after 1, 3, 6 and 12 months.

What are the possible benefits and risks of participating?

Participants may be protected against the effects of sleep bruxism (i.e. toothwear, dental fractures, dental sensitivity). There are no risks expected for those taking part in the study.

Where is the study run from?

University of Torino (Italy)

When is the study starting and how long is expected to run for?

May 2014 to February 2017

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

Who is the main contact?
Dr Andrea Deregibus

Contact information

Type(s)
Public

Contact name
Dr Andrea Deregibus

Contact details
CIR Dental School Lingotto
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
alignerbruxism2016

Study information

Scientific Title
Effects on sleep bruxism activity of orthodontic clear aligners 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 clear aligners.

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: 0089211

Study design
Single-centre randomized interventional trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Sleep bruxism

Interventions

A group of 40 patients will be screened for sleep bruxism with a validated portable device (Bruxoff®, OT Bioelettronica, Torino, Italia) before being randomly allocated (random number list software generated) into two different treatment groups.

Group 1: aligner group (AG) with 20 subjects who will be treated with orthodontic clear aligners (Invisalign®, Santa Clara, CA)

Group 2: placebo group (PG) with 20 subjects who will be treated with palatal splint with no tooth coverage

Both groups will be treated at the Department of Orthodontics of the Dental School of the University of Torino.

Both groups will be recorded with multiple nocturnal instrumental ECG/EMG recordings in order to screen and control possible variation in sleep bruxism activity. The ECG/EMG recording will be conducted with a three channels validate portable device for sleep bruxism diagnosis (Bruxoff®, OT Bioelettronica, Torino, Italy). Two channels will be used to acquire surface electromyography (sEMG) bilaterally from the masseter, and the third channel will be used to acquire the electrocardiographic activity (ECG). The three signals will be sampled at 800 Hz, with 8 bit resolution. The data will be stored on a MicroSD card as a binary file. The sEMG channels will be filtered between 10 and 400 Hz with gain 4300. The electrocardiographic (ECG) channel will be filtered between 15 and 160 Hz with gain 700. Surface EMGs from the masseter muscle of both sides will be 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 will be detected with a disposable bipolar electrode located on the left side of the thorax just below the pectoral muscles. At the beginning of the recording, the subjects will be asked to perform three maximum voluntary clenching (MVC) lasting 3 s each and separated by 10 s of rest. The greatest of the MVC measures will be used for normalizing the EMG values as a percent of MVC. Scoring on the Bruxoff recordings will be automatically performed by dedicated software (Bruxmeter®, OT Bioelettronica, 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. Moreover, instrumental evaluation allows to identify specific sEMG signals: tonic, phasic and mixed. The subjects will use the device and mount the electrodes at their homes without technical assistance, after prior

training. They will be provided with written instructions and a night-time telephone number to call in the event of difficulties.

For participants in both groups, at baseline and then after 1, 3, 6 and 12 months, nocturnal instrumental recordings of ECG/EMG activity will be recorded in home setting to detect variations in sleep bruxism activity.

Intervention Type

Device

Primary outcome measure

Sleep bruxism index, determined from Bruxmeter software at baseline, 1 month, 3 months, 6 months, and 1 year

Secondary outcome measures

EMG signals (tonic, phasic or mixed), measured with dedicated software at screening, 1, 3 and 6 months, and 1 year

Overall study start date

20/01/2014

Completion date

20/02/2017

Eligibility

Key inclusion criteria

1. Patients able to give their informed consent
2. Patients suffering from sleep bruxism
3. Good oral hygiene and periodontal status
4. Patients requiring orthodontic treatment
5. Adolescents (aged from 16 years) and adults (>18 years)

Participant type(s)

Patient

Age group

Mixed

Lower age limit

18 Years

Sex

Both

Target number of participants

40 patients

Key exclusion criteria

1. Patients suffering from neurological diseases
2. Patients suffering from signs/symptoms of tempormandibular disorders
3. Patients already wearing occlusal splints
4. Patients with orthodontic treatment in progress
5. Post traumatic patients
6. Patients suffering from other sleep disorders (i.e., sleep apnea, restless leg syndrome)

Date of first enrolment

20/04/2014

Date of final enrolment

20/12/2015

Locations

Countries of recruitment

Italy

Study participating centre**Dental School, Department of Orthodontics**

University of Torino

Via Nizza 230

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Sponsor information

Organisation

University of Torino

Sponsor details

CIR Dental School Lingotto

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Sponsor type

University/education

ROR

<https://ror.org/048tbm396>

Funder(s)

Funder type

University/education

Funder Name

Università degli Studi di Torino

Alternative Name(s)

University of Turin in Italy, University of Turin, Italy, Università di Torino, , University of Turin, UNITO

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Italy

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal in 2018

Intention to publish date

20/02/2018

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

IPD sharing plan summary

Available on request