The association between Sleep bruxism and Temporomandibular disorder Pain

Published: 02-07-2015
Last updated: 20-04-2024

1. How does muscle overloading expressed by pain effect SB characteristics?2. What SB characteristics are associated with jaw-muscle pain?3. Are SB and psychological stress contributing factors for TMD pain?

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON44258

Source
ToetsingOnline

Brief title
Sleep bruxism and Temporomandibular disorder Pain

Condition

- Other condition
- Muscle disorders

Synonym
jaw-muscle pain

Health condition

Sleep disorders (Sleep bruxism)

Research involving
Human

Sponsors and support

Primary sponsor: Academic Centre for Dentistry Amsterdam (ACTA)
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Jaw-muscle pain, Sleep bruxism

Outcome measures

Primary outcome

Experimental study.

The main study parameters for experimental study are five characteristics of SB activity.

1. Bruxism intensity (PSG). This defined as the strength of clenching the teeth. Bruxism intensity is calculated based on the root mean-square of the EMG signal from the masticatory muscles. Bruxism intensity will be measured by analyzing polysomnographic recordings using RemLogic (Embla, Ontario, Canada) and Bruxism Detector (ACTA custom made) software.

2. Bruxism duration (PSG). How long the patient clenches or grinds his teeth will be calculated as a sum of all SB episodes duration by analyzing polysomnographic recordings using RemLogic and Bruxism Detector software.

3. Amount of episodes per hour of sleep (PSG). This will be computed by analyzing polysomnographic recordings using RemLogic and Bruxism Detector software.

4. Rest time between episodes. We will analyze the distribution of SB episodes throughout the night using RemLogic and Bruxism Detector software.

Cross-sectional study

Muscle pain (Myalgia). This diagnosis will be based on the Extensive Clinical Examination Protocol of ACTA*s OPD Clinic. Criteria to evaluate the diagnosis of myalgia is in Inclusion criteria and based on Diagnostic Criteria for Temporomandibular Disorders (DC/TMD) for Clinical and Research Applications..

Longitudinal study (pilot)

Muscle pain and psychological stress. Presence of Muscle pain will be assessed by the questionnaire with visual analog scales (VAS) and using the Extensive Clinical Examination Protocol of ACTA*s OPD Clinic. Psychological stress experience will be recorded using the Patient Health Questionnaire 9 (PHQ-9).

Secondary outcome

Experimental study

Muscle pain.

Study description

Background summary

Sleep bruxism (SB) is a repetitive jaw-muscle activity characterized by clenching or grinding of the teeth and/or by bracing or thrusting of the mandible during sleep. Epidemiologic studies have reported that the prevalence of SB is highly variable * the reported percentages range from 3% to 41%. Generally, SB is thought to have a circular relationship with temporomandibular disorders (TMD): sleep bruxism causes pain due to overloading of the masticatory muscle, and this pain in turn provokes more bruxism activity. However, the data about the association between SB and TMD in the literature are not so straightforward, and depend largely on the diagnostic approach to SB. The controversy can easily be explained by the complicated nature of SB and TMD. On the one hand, controversial results in studying the SB-TMD association can be explained by the fact that previous studies dealt with SB patients who

already have TMD pain. Such a muscle pain may have an effect on the jaw-muscle activity by itself. Up to now, there are no papers that have studied the effect of jaw-muscle pain due to overloading on SB activity. In the experimental part we will study the effect of jaw-muscle pain due to overloading on SB.
On the other hand, as any muscle activity SB can be described by numbers of characteristics. The most important of them are duration of muscle activity, strength of muscle contractions, rest time between muscle contractions. Up to now, all previous studies have used only few characteristics of jaw-muscle activity to describe SB: the number of bruxism episodes per hour of sleep and sometimes the duration of bruxism episodes. The specific characteristics of jaw-muscle activity that may lead to muscle overloading have never been described. In the cross-sectional study we will investigate what specific characteristics of SB are associated with jaw-muscle pain.
Another possible reason for controversial results in studying the SB - TMD association is the fluctuating nature of both SB and TMD. A patient may have high SB activity at one night and lower at another. To study the SB * TMD association, it is therefore crucial to make multiple registrations. Moreover over factors, such as psychological stress, may have an effect on the presence of jaw-muscle pain. Hence the third part of the proposed research is a pilot longitudinal study that focused on the interaction between sleep bruxism, jaw muscle pain and psychological stress.

Study objective

1. How does muscle overloading expressed by pain effect SB characteristics?
2. What SB characteristics are associated with jaw-muscle pain?
3. Are SB and psychological stress contributing factors for TMD pain?

Study design

1. The first part of the research is the experimental study.
2. The second part is the cross-sectional study.
3. The third part is the longitudinal study (pilot).

Intervention

In the experimental part of the research we will provoke delayed-onset muscle soreness in 10 pain free bruxism patients using a custom made provocation device.
We need this experiment to study the effect of jaw muscle pain on sleep bruxism.

Study burden and risks

Participants will be exposed to the following procedures:

a) Provocation of delayed-onset muscle soreness (DOMS) in the experimental study. The provocation protocol is used since 2010. It is considered to be harmless: a few days after the provocation, no symptoms of DOMS are found anymore. In other words: the provoked muscle pain has a transient nature. For more details about DOMS provocation test see paragraph 5 *Treatment of subjects*.
b) Ambulatory polysomnographic (PSG) recording. For every participant, five PSG recordings will be made in the experimental study, two PSG recordings in the clinical study, and 6 PSG recordings in the longitudinal study. Polysomnography is a noninvasive, painless test. Complications are rare. The most common side effect is skin irritation caused by the medical patches used to attach test sensors to the skin. For more details about PSG recording see paragraph 6.2.1 in *Methods*.
c) Clinical examination according to the Extensive Clinical Examination Protocol of ACTA*s OPD Clinic. There are three examinations for the experimental study, one examination for the clinical study, and one examination for the longitudinal study. Clinical examination is a routine clinical procedure that is not associated with any risks for the patients. Extensive Clinical Examination Protocol of ACTA*s OPD Clinic is included in the Appendix.
e) The Diagnostic Questionnaire of the OPD Clinic. Every participant fills in the questionnaire before entering the study. This is part of the routine clinical procedure according to the Extensive Clinical Examination Protocol of ACTA*s OPD Clinic. The Diagnostic Questionnaire of the OPD Clinic is included in the Appendix.
f) Morning and evening questionnaires and PHQ-9. Participants fill in the questionnaires five times for the experimental study, two times for the clinical study, and twelve times for the longitudinal study . The questionnaires are included in the Appendix.
g) The Tampa Scale for Kinesiophobia for Temporomandibular Disorders (TSK-TMD) questionnaire for the experimental study. This questionnaire is filled in once by participants in the experimental study. TSK-TMD questionnaire is included in the Appendix.

Contacts

Public
Academic Centre for Dentistry Amsterdam (ACTA)

Gustav Mahler Laan 3004
Amsterdam 1081 LA
NL
Scientific
Academic Centre for Dentistry Amsterdam (ACTA)

Gustav Mahler Laan 3004
Amsterdam 1081 LA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Presence of clinical signs of sleep bruxism

Exclusion criteria

Sleep disorders, other than sleep bruxism; regular use of painkillers

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-10-2012
Enrollment:	90
Type:	Actual

Medical products/devices used

Generic name:	Custom-made device to provoke delayed-onset muscle soreness (does not have CE mark); Embla titanium
Registration:	No

Ethics review

Approved WMO Date:	02-07-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-05-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL48227.029.14