

Low level laser treatment for masticatory muscle pain

Submission date 28/08/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 10/09/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/11/2015	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Myofascial pain is a long-term pain disorder, in which pain, tenderness and muscle spasms are felt in facial muscles. The masticatory muscles include all of the muscles that are responsible for movement of the jaw. These muscles are often the most affected in cases of myofascial pain, as their involvement in chewing (mastication) means that they are used a lot. Two of the most common points where this pain is felt are the masseter muscle, which is the main muscle involved in chewing, and the temporalis muscle, which is involved in closing the mouth and moving the mouth from side to side when chewing. Low-level laser therapy (LLLT) is a treatment which uses specific wavelengths of light to stimulate the cells in the body that repair tissue, reduce inflammation, and reduce pain. This non-invasive treatment has proven to be very effective for treating back and neck pain, as well as other long term pain conditions. The aim of this study is to investigate whether applying LLLT to the point of greatest pain would help to reduce masticatory muscle pain.

Who can participate?

Adults with a diagnosis of myofascial pain and natural posterior occlusion (the teeth at the back of the mouth are aligned correctly).

What does the study involve?

Participants are randomly allocated into one of three groups. For participants in the first group, the low level laser is applied precisely and continuously to the places where pain is greatest in the related muscle. For participants in the second group, the laser is applied to three previously chosen points on the masseter muscle and three points on the temporalis muscle. For participants in the third group, the laser device is switched on, but not programmed to target any particular points. Levels of pain and movement range are assessed before and after the laser treatment.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

Istanbul University Faculty of Dentistry Department of Prosthodontics (Turkey)

When is the study starting and how long is it expected to run for?
September 2010 to October 2011

Who is funding the study?
Istanbul University Faculty of Dentistry Department of Prosthodontics (Turkey)

Who is the main contact?
Dr Bilge Gokcen-Rohlig

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Early results of low-level laser application for masticatory muscle pain: a double-blind randomized clinical study

Study objectives
Direct application of low-level laser therapy (LLLT) at the point of greatest pain would reduce muscle pain to a greater degree than would application at pre-established points and placebo.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Istanbul University Faculty of Medicine , 10/05/2012, ref: 2011/1272-639

Study design

Single-centre randomised controlled trial.

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Masticatory pain

Interventions

Participants were divided randomly into three age- and sex-matched groups:

1. Laser group (LGI) in which low level laser is applied precisely and continuously to the greatest points of pain in the related muscle (masseter and/or temporalis).
2. Laser group II (LGII) in which LLLT is applied in the same manner to three predetermined points on the masseter muscle (superior [MS], middle [MM], and inferior [MI] points) and three points on the temporalis muscle (anterior [TA], middle, and posterior points)
3. Placebo group (PG) in which the laser device was switched on, but not programmed.

Intervention Type

Device

Primary outcome(s)

Mandibular movement range (right, left and protrusion) before and after the assigned treatments, pain on palpation by masseter muscles on three points (superior, middle and inferior points), temporalis muscles on three points (anterior, middle and posterior points) and pressure pain thresholds for the same points by algometer.

Key secondary outcome(s)

Pressure pain thresholds of the examined muscles are investigated before and after each treatment via visual analogue score (VAS), before any after the treatments

Completion date

01/10/2011

Eligibility

Key inclusion criteria

1. Diagnosis of myofascial pain according to the Research Diagnostic Criteria for Temporomandibular Disorder (RDC/TMD)
2. Aged between 18–60 years
3. Natural posterior occlusion

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Disc displacement with reduction or without reduction with or without limited opening, arthralgia, arthritis, or arthrosis
2. General inflammatory connective tissue disease (e.g. rheumatoid arthritis)
3. Psychiatric disorder
4. Tumour
5. Heart disease or pacemaker
7. Pregnancy
8. Symptoms that could be referred to other orofacial region diseases (e.g. toothache, neuralgia, migraine)
9. Treatment or medication use for headache or bruxism in the last 2 years
10. Local skin infection over the masseter muscle

Date of first enrolment

01/09/2010

Date of final enrolment

01/10/2011

Locations**Countries of recruitment**

Türkiye

Study participating centre

Istanbul University Faculty of Dentistry Department of Prosthodontics

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Capa

Istanbul

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34390

Sponsor information**Organisation**

Istanbul University Faculty of Dentistry Department of Prosthodontics

ROR

<https://ror.org/03a5qrr21>

Funder(s)

Funder type

University/education

Funder Name

Istanbul University Faculty of Dentistry Department of Prosthodontics

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/10/2015		Yes	No