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Low level laser treatment for masticatory muscle pain

Submission date
28/08/2015

Recruitment status
No longer recruiting

Registration date
10/09/2015

Overall study status
Completed

Last Edited
04/11/2015

Condition category
Signs and Symptoms

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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), temporals muscles on three points (anterior, middle and posterior points) and pressure pain thresholds for the same points by algometer.

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

Overall study start date
01/09/2010

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30

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. Hearth 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
Türkiye
34390

Sponsor information

Organisation
Istanbul University Faculty of Dentistry Department of Prosthodontics

Sponsor details
Istanbul University Faculty of Dentistry Department of Prosthodontics
Capa
Istanbul
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34390

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03a5qrr21

Funder(s)

Funder type
University/education

Funder Name
Istanbul University Faculty of Dentistry Department of Prosthodontics

Results and Publications

Publication and dissemination plan
Manuscript has been submitted to BMC Oral Health.

Intention to publish date

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