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Laser Therapy and Transcutaneous Electrical Nerve Stimulation (TENS) in Temporomandibular Disorder

Submission date 20/02/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 28/02/2011	**Overall study status** Completed	
Last Edited 28/02/2011	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

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
Laser Therapy and Transcutaneous Electrical Nerve Stimulation (TENS) in the treatment of Temporomandibular Disorder: A randomised controlled trial

Study objectives
Temporomandibular disorders affect the masticatory muscles, the TMJ and adjacent structures. The main symptomatology is myofascial pain and mandibular dysfunction. One of the main causes of pain is a muscle spasm that may be generated by muscle distension, contraction or fatigue. These conditions are caused by muscle hyperactivity, which, in turn, may be caused by bruxism or emotional factors, such as stress. The incidence of TMDs has been increasing, especially among women.

Both laser therapy and transcutaneous electrical stimulation are effective in the treatment of Temporomandibular Disorder (TMD)
1. Transcutaneous electrical stimulation is more effective than laser therapy in temporomandibular disorders analgesia
2. Laser therapy produces a more significant improvement in joint mobility of the temporomandibular joint (TMJ) in relation to transcutaneous electrical stimulation and the control group
3. The combination of laser therapy and transcutaneous electrical stimulation produced a significant improvement in quality of life of patients TMD.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Human and Animal Research Ethics Committee of the Lutheran University of Brazil (Universidade Luterana do Brasil), approved on 5th July 2010, reference number: 2010-232H

Study design
Randomised clinical equivalence trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Temporomandibular Disorders

Interventions
1. The patients were randomly divided into four groups:
1.1. Control group, with 9 subjects, receiving continuous dental treatment
1.2. Group laser, with 8 subjects, receiving dental treatment plus low-frequency laser therapy
1.3. Group TENS, with 6 subjects, receiving dental treatment, in addition to TENS
1.4. Group laser + TENS, with 7 subjects, receiving dental treatment plus transcutaneous electrical nerve stimulation and laser therapy

2. Laser Therapy Protocol
A previously calibrated, low-level gallium arsenide (AsGa) endophoton laser was used (KLD®, Amparo, SP, Brazil), with a wavelength of 904 nm, energy density of 6 J/cm2, average power of 50 mW and beam area of 0.035 cm2, with continuous emission for 36 seconds per point. Laser application was performed punctually and in contact with the surface, perpendicular to the skin and bilaterally.

3. TENS Protocol
For the application of TENS, previously calibrated TENS Vif four 993 equipment (Quark®), manufactured in Piracicaba, in the state of São Paulo, Brazil, was used. Two channels with four rectangular silicon-carbon transcutaneous electrodes (3 cm x 5 cm) were used. These electrodes were placed bilaterally on the preauricular region and on the masseter muscle, with one channel for the right side and one for the left side. The adopted parameter was 40 Hz frequency, modulated at 50%, pulse width of 200 μs and motor threshold intensity, which was identified by visible muscle contraction.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. All treatment groups showed an improvement in pain, according to the Visual Analogue Scale (VAS), after physiotherapy. The laser (p=0.001) and laser + TENS groups were significantly better (p=0.005) than the control group.
2. According to the RDC/TMD questionnaire, there was an improvement in the laser (p=0.016) and laser + TENS (p=0.008) groups compared to the
control group.
3. Surface electromyography (sEMG) showed improvements in all treatment groups when comparing pre-treatment and post-treatment, but only the laser + TENS group showed improvement in both the masseter and temporal muscles in relation to the control group. The range of joint motion significantly increased only for the mandible retraction movement in the laser group (p=0.003).

Secondary outcome measures
1. There were no significant changes of the variables before and after treatment in the control group. Only the variable pain, measured by the VAS, increased from 2.0 points in the initial assessment to 4.44 points in the final assessment.
2. All treatment groups showed a significant improvement in pain, according to the VAS, after

treatment. The laser + TENS group had a mean initial score of five, which was reduced to one in the final assessment. In relation to the control group, only the laser and laser + TENS groups had significantly lower values (in the laser group, p=0.001; in the laser + TENS group, p=0.005).
3. For the pain results obtained by the RDC/TMD axis II questionnaire, only the TENS and laser + TENS groups were different in relation to the control. Within the groups, there were improvements in pain of 17.5 points in the initial assessment to 13.83 points after treatment in the TENS group (p=0.016) and of 17.86 points to 13.43 points in the laser + TENS group (p=0. 008).
4. In relation to the electromyographic activity of the masticatory muscles, the laser + TENS group showed significantly better mean values in relation to the control group in the activation of the left temporal muscle (p=0.023). For the right temporal muscle, the laser and TENS groups showed significant scores in relation to the control group (p=0.043 and p=0.05, respectively). For the right masseter muscle, the TENS and laser + TENS groups showed significantly greater electrical activity than the control group. Finally, the left masseter muscle showed similar results to the right masseter muscle, and activity was significantly greater in the TENS and laser + TENS groups. However, all treatment groups showed increased electrical activity in the masseter and temporal muscles in relation to the initial assessment.
5. The range of motion of the temporomandibular joint showed significant improvement during the mandibular retraction movement only in the laser group, increasing from 6.58 degrees in the initial assessment to 11.73 degrees in the final assessment (p=0.003) and during the opening movement only in the laser + TENS group, in which there was an improvement from 12.52 degrees in the initial assessment to 16.79 degrees in the final assessment (p=0.02).

Overall study start date
01/08/2010

Completion date
01/12/2010

Eligibility

Key inclusion criteria
Temporomandibular joint dysfunction in patients with dental treatment

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
58 patients with a diagnosis of temporomandibular disorder

Key exclusion criteria
1. Volunteers that did not suffer from pain in the masticatory muscles,
2. Volunteers who experienced changes in surface sensitivity
3. Volunteers who had had some type of physical therapy treatment for TMD

Date of first enrolment
01/08/2010

Date of final enrolment
01/12/2010

Locations

Countries of recruitment
Brazil

Study participating centre
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Sponsor information

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Sponsor type
University/education

ROR
https://ror.org/00kde4z41

Funder(s)

Funder type
University/education

Funder Name
Lutheran University of Brazil (Universidade Luterana do Brasil) (Brazil)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration