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Investigating the effect of photobiomodulation on pain and patient's daily activities after surgical extraction of impacted mandibular third molar

Submission date
22/02/2024

Recruitment status
No longer recruiting

Registration date
26/02/2024

Overall study status
Completed

Last Edited
26/02/2024

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Several postoperative complications have been reported with the surgical extraction of impacted third mandibular molars; including pain, edema, trismus, and/or functional limitation. Anti-inflammatory agents are usually prescribed for these postoperative complications. However, there are various reported side effects with the use of these drugs. In addition, their prescription is contraindicated in some patients with some conditions. Several adjunctive modalities to surgical procedures are proposed as a trial to decrease postoperative discomfort, such as the use of piezosurgery, cryotherapy, and photobiomodulation (PBM). PBM as an adjunctive modality has been widely investigated. In the literature, it has been recently observed that the combined protocols of PBM (i.e. intraoral and extraoral) are more efficient than only intraoral or extraoral protocol. In addition, it has been observed that the wavelengths used for PBM are mostly in the red and near-infrared wavelength range. To our knowledge, there is no study of PBM using a combination of different wavelengths in combined protocols (i.e. intraoral and extraoral). The study aims to evaluate the effectiveness of the single-session intraoral and extraoral PBM using a combination of different wavelengths on pain and the patient's daily activities following the surgical extraction of the impacted third mandibular molar.

Who can participate?
Patients aged between 18 and 65 years old referred to the Department of Oral Sciences and Maxillofacial Surgery, Sapienza University of Rome who will undergo a surgical extraction of partially bony impacted mandibular third molar.

What does the study involve?
The study involves immediate intraoral and extraoral PBM single sessions after the surgical extraction on test group patients. While the patients of the control group are subjected to the same surgical extraction without PBM application.

What are the possible benefits and risks of participating?
The possible benefits are a significant reduction of pain, improvement of the daily social, physical, and speaking activities, and reduction of possible need for painkillers intake in the postoperative period (7 days). There are no reported risks with the PBM application.

Where is the study run from?
Department of Oral Sciences and Maxillofacial Surgery, Sapienza University of Rome (Italy)

When is the study starting and how long is it expected to run for?
July 2017 to December 2022

Who is funding the study?
Sapienza University of Rome (Italy)

Who is the main contact?
Prof. Umberto Romeo
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Public, Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
775/17

Study information

Scientific Title
The impact of single-session intra- and extraoral photobiomodulation on pain and patient’s daily activities after surgical extraction of impacted mandibular third molars

Study objectives
A single session of intraoral and extraoral photobiomodulation reduces significantly pain and improves the daily activities in patients who underwent surgical extraction of the impacted third mandibular molar than controls.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 14/09/2017, Ethics Committee of "SAPIENZA" University (Viale del Policlinico 155, Rome, 00161, Italy; +39 0649979822; comitato.etico@policlinicoumberto1.it), ref: 4687

Study design
Single-centre randomized pilot study

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Improvement in pain and daily activities in patients who undergo surgical extraction of impacted mandibular third molar

Interventions
The patients are randomly divided into two groups using sealed envelopes:
1. The Test Group (TG) consists of patients subjected to immediate postoperative intra- and extraoral photobiomodulation (PBM) using laser device K-Laser Blu Dental that emit three wavelengths in combination; 445 (±5) nm, 660 (±5) nm, and 970 (±5) nm. The extraoral PBM parameters are a power of 550mW and a spot area of 5cm2. The intraoral PBM parameters are power of 200mW and spot area of 2cm2.
2. The Control Group (CG) consists of the patients not subjected to PBM.

Intervention Type

Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
K-Laser Blu Dental device

Primary outcome(s)
Pain measured using a numeric rating scale (NRS) 4 times on 0, 1, 3, and 7 days after surgical intervention

Key secondary outcome(s))
1. Painkiller intake, defined as the number of tablets of ibuprofen 400mg, measured using a custom-made questionnaire on day 7 after surgery
2. Patient’s daily activities measured using a custom-made questionnaire on day 7 after surgery

Completion date
07/12/2022

Eligibility

Key inclusion criteria
1. Patients undergoing the surgical extraction of a partially bony impacted mandibular third molar
2. Normal healthy patients of both genders
3. Age age ≥ 18 years
4. No systemic disorders
5. No smoking habits
6. Absence of pericoronitis
7. No allergy to anesthetic solutions.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
22

Key exclusion criteria
1. Patients refuse to participate in the study
2. Pregnant or lactating patients
3. Patients subjected to anti-inflammatory drugs, or antibiotic therapy within 2 weeks before the surgical intervention
4. Patients with systemic disorders
5. Patients who do not complete the designed questionnaires of the study

Date of first enrolment
03/01/2022

Date of final enrolment
30/11/2022

Locations

Countries of recruitment
Italy

Study participating centre
Department of Oral Sciences and Maxillofacial Surgery, Sapienza University of Rome
Via Caserta 6
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Sponsor information

Organisation
Sapienza University of Rome

ROR
https://ror.org/02be6w209

Funder(s)

Funder type
University/education

Funder Name
Sapienza Università di Roma

Alternative Name(s)
Sapienza University of Rome, Università degli Studi di Roma "La Sapienza”, Sapienza-Università di Roma, Sapienza, Uniroma1

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Italy

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed during the current study are available upon request from Prof. Umberto Romeo, umberto.romeo@uniroma1.it. The data of the study is only conserved for 10 years in the Department of Oral Sciences and Maxillofacial Surgery, Sapienza University of Rome. The personal information of the participants is present only in the form of dental clinical charts protected by the privacy policy of the university. An informed consent is signed by each participant and conserved in his/her clinical chart. The individual data are deidentified by linking them only to the chart number and a new code for each study participant. The datasets generated and analyzed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Stored in non-publicly available repository, Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Statistical Analysis Plan			26/02/2024	No	No