

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/02/2024	Overall study status Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 26/02/2024	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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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Contact information

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

University/medical school/dental school

Study type(s)

Efficacy

Participant information sheet

No participant information sheet available

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

Pharmaceutical study type(s)

Not Applicable

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

K-Laser Blu Dental device

Primary outcome measure

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

Secondary outcome measures

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

Overall study start date

25/07/2017

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 ≥ 18 years
4. No systemic disorders
5. No smoking habits
6. Absence of pericoronitis
7. No allergy to anesthetic solutions.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

30

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

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Sponsor information

Organisation

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Sponsor type

University/education

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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

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

15/03/2024

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?
Statistical Analysis Plan			26/02/2024	No	No