Pre-injection analgesic effects of low-level laser/light therapy (LLLT) in preparation for third molar surgery

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The aim of this study is to evaluate the analgesic effects of LLLT on maxillary and mandibular block pre-injection sites in patients scheduled for elective third molar removal.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Soft tissue therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON41371

Source
ToetsingOnline

Brief title
LLLTxM3

Condition

- Soft tissue therapeutic procedures

Synonym
removal of wisdom teeth, third molar extraction

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: analgesia, LLLT, third molar extraction

Outcome measures

Primary outcome

Heart rate and galvanic skin response (sweat secretion) response.

Secondary outcome

Short questionnaire before the start of treatment and 2 questions after

completion.

Study description

Background summary

Removal of wisdom teeth is a routine procedure in oral and maxillofacial surgery. [1] Generally, removal of third molars is a treatment for impacted teeth or teeth that fail to erupt during the normal course of growth and development. Moreover, depending on the anatomically available space on the dental arches and the fate of the erupting element, another rationale for removing third molars before complete root formation is to prevent the likelihood of nerve damage and other oral complications, and maintenance of adequate orthodontic dental alignment.

Pain control, is necessary during removal of third molars and this is established by injecting a local anesthetic. The injection itself can be painful, and topical anesthesia before local anesthesia might influence the pain during needle penetration and infiltration injection. Topically applied local anesthetics only provide an anesthetic effect on the mucosal epithelial surface and does not blunt the effects of discomfort perceived by the patients related to both needle infiltration and tissue displacement by the anesthetic fluid load in the anatomical cross-sectional plain. However, refining the experience of preoperative preparation by reducing additional pharmacological usage has the advantage that patients with dental fears and anxiety can feel more at ease and project a serene attitude towards either periodic visits to their dentist or facilitating important decisions regarding maxillofacial procedures with confidence.

Concern about pain and anxiety associated with needles dominates preferences

for dental anesthesia; the overwhelming preference for a non-injectable anesthetic reveals a strong clinical need for alternatives. A conservative pharmacological approach towards pre-injection management of local anesthesia could promote both metabolic stability in the tissue intended for treatment, by endorsing swift postoperative tissue recovery and stabilization, and eliminating unpleasant tastes associated with topical anesthetics. An alternative to topical agents may lie in harnessing the beneficial effects derived from light energy. Low-level laser/light therapy (LLLT) is the application of light, in the form of either a low power laser or light-emitting diodes (LEDs), [2] to promote tissue repair and regeneration, [3-6] reduce inflammation, and induce analgesia. [7-12] Unlike other laser-mediated treatments, LLLT is not an ablating or heat-based therapy; it is more akin to photosynthesis. Current knowledge of clinical applications of LLLT in dentistry is limited, but its applications are well documented for musculoskeletal applications. [13-16] Pain control in dentomaxillofacial perioperative settings has focused primarily on the effects of LLLT in postoperative pain management associated with premolar and third molar extractions. [17-20] Frustratingly, a consensus on reporting light-related parameters does not exist, which makes it very difficult to reproduce results that can be used to harness the benefits of LLLT clinically. [21] Research addressing acute pain management effects remain unexplored as they apply to light therapy in daily routine dental practice. [22] Additionally, interests based on drug-free analgesic management in dentistry and oral medicine have already begun to yield interesting studies focusing on pain management and healing associated with orthodontic and periodontal treatments by LLLT. [23-25] We propose to assess the effects of LLLT on injection sites before local anesthetic injections are administered to determine if the patient experiences any laser induced analgesic effects. For clarity we wish to assert that this research protocol will not bring any discomfort to the participant, will not intervene with the standard care protocols associated with third molar extraction procedures, does not aim to address any queries associated with specific disease or health issues, and finally local infiltration anesthetic injections will be administered after LLLT as this is standard operating procedures for surgical removal of third molars.

Study objective

The aim of this study is to evaluate the analgesic effects of LLLT on maxillary and mandibular block pre-injection sites in patients scheduled for elective third molar removal.

Study design

A double-blind randomized study with a control group (RCT).

Study burden and risks

Besides the treatment the patient will undergo, there are no risks associated with this study and the participants will only be burdened with answering a short questionnaire. Administering LLLT and filling-in the questionnaire will take on average only between 10-15 min.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-Patients referred to the Department of Oral & Maxillofacial Surgery of the Amstelland Hospital (Ziekenhuis Amstelland) for extraction of third molars
-Patients with no previous history of oral diseases
-Patients with an ASA Score 1 or 2 (excluding pregnancy)
-Patients that signed an informed consent form

-Patients >= 18 years

Exclusion criteria

-Patients with a previous history of oral disease
-Patients that did not sign an informed consent form
-Patients with an ASA Score 3 or higher
-Patients < 18 years

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-03-2015
Enrollment:	244
Type:	Actual

Medical products/devices used

Generic name:	Phototherapy systems (LX2m)
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	21-01-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL46371.018.14