Parameters in fractional laser assisted delivery of topical anesthetics: role of laser type, laser settings, type of anesthetic and occlusion time

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Epidermal and dermal conditions
Study type	Interventional

Summary

ID

NL-OMON42648

Source
ToetsingOnline

Brief title
Fractional laser assisted delivery of anesthetics III

Condition

- Epidermal and dermal conditions

Synonym
Not applicable

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Drug delivery, Fractional laser, Topical anesthesia

Outcome measures

Primary outcome

The main study endpoint in group A is pain, as scored on a VAS from 0-10 (0: no pain; 10: worst imaginable pain) directly after a pain stimulus on test regions pretreated with either the fractional CO2 or the Er:YAG laser.

The main study endpoint in group B is pain, as scored on a VAS from 0-10 (0: no pain; 10: worst imaginable pain) directly after a pain stimulus on fractional laser pretreated test regions anesthetized with either AHES or LTC.

Secondary outcome

Group A: Pain, as scored on a VAS from 0-10 (0: no pain; 10: worst imaginable pain) directly after a pain stimulus on test regions pretreated with either 5% or 15% density.

Group B: Pain, as scored on a VAS from 0-10 (0: no pain; 10: worst imaginable pain) directly after a pain stimulus on the test regions after 5, 15 or 25 minutes occlusion time of the anesthetic.

Group A and B: Pain, as scored on a VAS from 0-10 (0: no pain; 10: worst imaginable pain) directly after pretreatment with each different laser type or

setting.

Study description

Background summary

In dermatology, many minor surgical and laser procedures are carried out under local anesthesia of the skin. Anesthesia using topical formulations is time consuming, as the anesthetic has to be applied at least one hour before treatment, and is often only partially effective. On the other hand infiltration anesthesia is often associated with discomfort. In the past years, enhanced and accelerated penetration of various topically applied substances, including photosensitizers and anesthetics, has been proven by pretreatment of the skin with an ablative fractional laser (AFXL), creating a pattern of microscopic ablation channels. In a previous pilot study performed at our institute, we demonstrated that effective anesthesia could be achieved within ten minutes after application of a topical anesthetic on skin pretreated with AFXL at painless settings (METC 2014_139). However, little is still known about the role of the type of fractional laser used (e.g. CO2 or Er:YAG laser), the laser settings, the type of anesthetic and the occlusion time on the efficacy of the anesthesia.

Study objective

The primary objectives of the present study are to compare the effect of pretreatment with two different fractional laser modalities (CO2 and Er:YAG laser) on topical anesthesia and to compare the anesthetic effect of two different topical anesthetics on fractional laser pretreated skin.

Secondary objectives are to assess the role of the laser settings and occlusion time.

Study design

Prospective, single blinded, randomized, intra subject controlled study.

Intervention

Subjects will be divided into two groups. In group A, four test regions on each subject*s back will be randomly allocated to pretreatment with the fractional CO2 laser at 5% (I) or 15% density (II) or pretreatment with the fractional Er:YAG laser at 5% (III) or 15% density (IV). After pretreatment, articaine hydrochloride 40 mg/ml + epinephrine 10 *g/ml solution (AHES) will be applied on the test regions with 15 minutes occlusion time. In group B, six test

regions will be pretreated with the fractional CO2 laser at 15% density. These regions will be randomly allocated to application of AHES for 5 (I), 15 (II) and 25 minutes (III) or application of lidocaine 70 mg/g + tetracaine 70 mg/g cream (LTC) for 5 (IV), 15 (V) or 25 minutes (VI). After the occlusion time, a single pulse with the CO2 laser (5% density; 50mJ) will be applied on each test region as a harmless standardized pain stimulus. In addition, a reference pain stimulus with the CO2 laser at the same settings will be given on unanesthetized skin. Subjects will be asked to indicate pain on a visual analogue scale (VAS) from 0-10 (0: no pain; 10: worst imaginable pain) directly after each pain stimulus.

Study burden and risks

Subjects participating in the study will be requested to visit the treatment center once. The time investment will be approximately 45 minutes. Fractional laser therapy is a minimally invasive procedure. At the settings used for pretreatment, no pain is usually experienced by subjects. Without the use of an anesthetic, the CO2 laser induced pain stimulus at 50 mJ/microbeam is felt as a firm sting for shorter than one second. Thereafter, a burning sensation may be felt for approximately one minute. Local side effects of fractional laser treatment at the settings used in this study are erythema (always; 1-2 weeks) and swelling (occasionally, 1-4 days).
All together, the burden due to this study is small, side effects are local, temporary and mild. Systemic side effects are not expected with the doses of topical anesthetics that will be used in this study. In earlier studies, safe blood serum concentrations of lidocaine could be maintained following fractional laser pretreatment of much larger areas of skin. Subjects will receive a reasonable compensation for the time invested.

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

Fitzpatrick skin type I or II
Age *18 years
Subject is willing and able to give written informed consent

Exclusion criteria

History of keloid or hypertrophic scar formation or complicated wound healing
Presence of any active skin disease
Known allergy to local anesthesia
Pregnancy or lactation
Incompetency to understand what the procedure involves
Current complaints of chronic pain or other alterations in pain sensation (e.g. due to diabetes mellitus or leprosy)
Current treatment with systemic analgesics or other medication that can influence pain sensation
Current treatment with anticoagulants
Fitzpatrick skin type III-VI
Excessive sun tan

Study design

Design

Study type: Interventional

Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-03-2016
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	fractional CO2 laser (Ultrapulse;DeepFX handpiece); fractional Er:YAG laser (P.L.E.A.S.E. Profession
Registration:	Yes - CE intended use
Product type:	Medicine
Brand name:	Pliaglis cream
Generic name:	lidocaine 70 mg/g and tetracaine 70 mg/g
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Ultracain DS forte
Generic name:	articaine hydrochloride 40 mg/ml and epinephrine 10 □g/ml
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	28-09-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-11-2015
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
EudraCT	EUCTR2015-002289-21-NL
CCMO	NL53766.018.15