Fractional CO2 laser assisted delivery of topical anesthetics: a randomized controlled pilot study

Published: 04-08-2014
Last updated: 20-04-2024

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

Summary

ID

NL-OMON40699

Source
ToetsingOnline

Brief title
Fractional laser assisted delivery of anesthetics

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 parameter is pain, as scored on a VAS from 0-10 (0: no pain; 10:

worst imaginable pain) directly after each pain stimulus.

Secondary outcome

N/A

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 and is not tolerated by patients who are for example needle phobic. In the past years, enhanced and accelerated penetration of various topically applied substances, including photosensitizers, has been proven by pretreatment of the skin with a fractional laser, creating a pattern of microscopic ablation craters. This improvement in drug penetration seems to be regardless of ablation crater depth. There is limited evidence that transepidermal lidocaine delivery can be increased by fractional laser pretreatment. These findings might suggest that local anesthesia of the skin may be achieved by applying an anesthetic drug topically on a skin surface pretreated with a fractional laser. However, the exact influence of ablative fractional laser pretreatment on the efficacy of topically applied anesthetics has never been quantitatively established. Furthermore, little is known about the role of the formulation of the topical drug delivered using this method.

Study objective

The primary objective of this study is to assess the analgesic effect of fractional carbon dioxide laser assisted delivery of two topical anesthetics (articaine hydrochloride 40 mg/ml and epinephrine 10 µg/ml solution (AHES) and

eutectic mixture of lidocaine 25 mg/g and prilocaine 25 mg/g cream (EMLA cream) compared to application of these anesthetics without fractional laser pretreatment.

The secondary objective is to compare the efficacy of these two different anesthetics, when applied according to the fractional laser drug delivery principle.

Study design

Prospective, single blinded, randomized, controlled, within subject, pilot study.

Intervention

In each subject, four test regions on subject*s back of 1x1 centimeter will be randomly allocated in a 2x2 design to (1) ablative fractional laser (AFXL) pretreatment (5% density, 2.5 mJ/microbeam) followed by topical application of AHES, (2) AFXL pretreatment followed by application of EMLA cream, (3) sham AFXL followed by application of AHES on the intact skin and (4) sham AFXL followed by application of EMLA cream on the intact skin. Sham AFXL will be done by delivering an AFXL pass at 5% density and 2.5 mJ/microbeam right adjacent to the region of AHES or EMLA application on the intact skin. After ten minutes incubation time, an AFXL pass will be given as a pain stimulus at each test region with 5% density and 35 mJ/microbeam. 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 20 minutes. Fractional carbon dioxide laser therapy is a minimally invasive laser procedure with FDA approval for the device. At the settings used for pretreatment, no pain is usually experienced by subjects. Without the use of an anesthetic, the pain stimulus at 35 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
Patient 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 lepra)
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):	18-09-2014
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	fractional CO2 laser
Registration:	Yes - CE intended use
Product type:	Medicine
Brand name:	EMLA cream
Generic name:	eutectic mixture of lidocaine 25 mg/g and prilocaine 25 mg/g cream

Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Ultracain DS forte
Generic name:	articaine hydrochloride 40 mg/ml and epinephrine 10 µg/ml
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	04-08-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-08-2014
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	EUCTR2014-001816-20-NL
CCMO	NL48655.018.14