Fractional CO2 laser assisted topical articaine anesthesia vs. topical EMLA administration: a randomized controlled study

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

Summary

ID

NL-OMON42101

Source
ToetsingOnline

Brief title
Fractional laser assisted topical anesthesia

Condition

- Epidermal and dermal conditions

Synonym
acne scars, traumatic scars

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

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

Intervention

Keyword: acne scars, fractional laser, local anesthesia, traumatic scars

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 fractional laser treatment of each test

region.

Secondary outcome

n.v.t.

Study description

Background summary

In laser dermatology, many 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. In for example fractional laser treatment of acne scars or traumatic scars, where relatively aggressive laser settings are required, topical anesthesia may be insufficiently effective. On the other hand infiltration anesthesia is often associated with discomfort and is not tolerated by patients who are for example needle phobic. This is of particular importance when larger areas of skin have to be infiltrated. In this case maximum dosage is also a limiting factor. Earlier research has shown that topically applied drugs can be effectively delivered to the dermis by pretreating the skin with an ablative fractional laser at low settings. Hence, an equal distribution of the drug can be achieved in the tissue. When topically applied local anesthetics can be delivered to deeper skin layers, this implicates a relatively simple and painless method of local skin anesthesia. Relatively large areas of skin can then be anesthesized with low doses of topical anesthetic. This technique could be used in various cutaneous surgical and laser procedures.

Study objective

The objective of this study is to assess the efficacy of skin anesthesia using fractional laser assisted delivery of articaine hydrochloride 40 mg/ml and epinephrine 10 µg/ml solution compared to standard anesthesia with topical eutectic mixture of lidocaine 25 mg/g and prilocaine 25 mg/g cream (EMLA cream).

Study design

Prospective, open label, randomized controlled, within patient trial

Intervention

In each patient, the lesion will be divided into two comparable regions during the visit prior to the therapeutic fractional laser treatment. These regions will then be randomly allocated to either standard anesthesia with EMLA cream (control region; region I) or ablative fractional laser assisted delivery of articaine hydrochloride 40 mg/ml en epinephrine 10 µg/ml solution (intervention region; region II). Patients will be asked to apply EMLA cream at region I under occlusion two hours prior to the therapeutic laser treatment. Fifteen minutes before the therapeutic laser treatment, the skin of region II will be pretreated with the fractional carbon dioxide laser (15% density, 2.5 mJ/microbeam). Directly following fractional laser pretreatment, articaine hydrochloride 40 mg/ml en epinephrine 10 µg/ml solution will be topically applied under occlusion at region II for 15 minutes. Subsequently treatment of both regions will be performed with the same fractional carbon dioxide laser at the settings used in routine clinical practice. Directly after this therapeutic laser treatment, patients will be asked to indicate pain on a visual analogue scale (VAS) from 0-10 (0: no pain; 10: worst imaginable pain) per test region.

Study burden and risks

Participation in the study requires minimal extra time investment from patients. 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 or other side effects are usually experienced by subjects. The dosages of articaine hydrochloride 40 mg/ml and epinephrine 10 µg/ml solution will be below half of the maximum dosage, so that the occurence of systemic side effects will be very unlikely. In earlier studies, safe blood serum concentrations of lidocaine could be maintained following fractional laser pretreatment of large areas of skin.

When anesthesia by fractional laser assisted delivery of articaine hydrochloride 40 mg/ml and epinephrine 10 µg/ml solution (intervention) appears to be less effective than standard anesthesia using EMLA cream (control), the therapeutic fractional laser treatment may be more painful than it would be in routine clinical practice. Based on preliminary data, this scenario seems

unlikely. Subjects can withdraw from the study at any moment. For any further treatment sessions, patients are allowed to choose the most favorable method of topical anesthesia.

In conclusion, as dosing of the anesthetics is relatively low and fractional laser pretreatment will not lead to significant side effects, we believe that the risks are negligible for the subjects participating in this study.

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 with acne scars or traumatic scars scheduled for treatment with the fractional carbon dioxide laser
Age >=18 years

Patient is willing and able to give written informed consent

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-06-2015
Enrollment:	21
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:	30-09-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-02-2015
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	EUCTR2014-001988-12-NL
CCMO	NL49394.018.14