A double blind randomized controlled trial comparing the efficacy of 7% lidocaine / 7% tetracaine cream versus 2,5% lidocaine / 2,5% prilocaine cream for local anaesthesia during laser treatment of acne keloidalis nuchae and tattoo removal.

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To compare the efficacy of 7% lidocaine / 7% tetracaine cream and 2,5% lidocaine / 2,5% prilocaine cream in reducing self-reported pain during a single laser procedure in the treatment of acne keloidalis nuchae and tattoo removal.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Skin appendage conditions
Study type	Interventional

Summary

ID

NL-OMON41973

Source
ToetsingOnline

Brief title
Comparison of two anaesthetic creams during lasertreatment

Condition

- Skin appendage conditions

Synonym
2. acne keloidalis nuchae, laser treatment of: 1. tattoos

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: - 2, - 7% lidocaine / 7% tetracaine cream, - dermatology, - laser, 5% lidocaine / 2, 5% prilocaine cream

Outcome measures

Primary outcome

Self-reported pain (10 point visual analog scale).

Secondary outcome

- adequate pain relief (yes/no);

- willingness to spend 25 euro for the best pain relief.

Study description

Background summary

The product most widely used for local anaesthesia during laser procedures for dermatological indications is a combination of 2,5% lidocaine and 2,5% prilocaine cream (EMLA®) and can be considered the gold standard. However, for some indications, the anaesthetic effect is not sufficient to allow a pain free and comfortable laser procedure. A newly developed self-occlusive topical 7% lidocaine / 7% tetracaine anesthetic cream (Pliaglis®) approved by the Food and Drug Administration (FDA) and European Drug Agency (EMA) is marketed to provide better local anesthesia for patients undergoing (superficial) dermatological procedures. This formulation contains the highest concentration of active anesthetic ingredients available in a topical cream and has shown superior efficacy in pain reduction versus placebo in several dermatological indications. However, apart from a single study comparing the efficacy of 7% lidocaine / 7% tetracaine cream versus 2,5% lidocaine / 2,5% lidocaine cream in pain reduction for (a single pass) CO2 laser resurfacing, no head-to-head studies have been performed for any of the other dermatological indications.

Therefore, in this study we will compare the efficacy of 7% lidocaine / 7% tetracaine cream with 2,5% lidocaine / 2,5% prilocaine cream in pain reduction during laser hair removal in acne keloidalis nuchae and tattoo removal; two dermatological conditions, which carry a high need for pain relief.

Study objective

To compare the efficacy of 7% lidocaine / 7% tetracaine cream and 2,5% lidocaine / 2,5% prilocaine cream in reducing self-reported pain during a single laser procedure in the treatment of acne keloidalis nuchae and tattoo removal.

Study design

Double-blind randomised controlled trial with split lesion design.

Intervention

The treatment area will be divided in two equal parts with white markings. Between this two areas an area of 1cm will be marked. This area will be left untreated, to avoid possible spill-over effects of the two anaesthetic creams. Sixty minutes before starting the laser treatment 7% lidocaine / 7% tetracaine cream will be applied on one part and 2,5% lidocaine / 2,5% prilocaine cream will be applied on the other part.

Study burden and risks

Patients who are referred to the department for laser treatments are asked to participate in this study. The study will not require any extra visits for the participants. Patients will be asked to fill in questionnaires to:
- assess the severity of pain experienced (VAS score) during laser treatment,
- evaluate whether the pain relief is adequate and,
- evaluate the amount of money patients would be willing to pay for the cream that
provided the *best* pain relief.
A potential benefit for the participants could be enhanced local anaesthesia during laser treatment. Both anaesthetic creams are registered to provide local anaesthesia and are reported to have minimal side effects.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Burg. s□Jacobplein 51
Rotterdam 3015 CA
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Burg. s□Jacobplein 51
Rotterdam 3015 CA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Subject has provided written informed consent;;• Subject is >= 18 years of age at time of screening;;• Group A: subjects with acne keloidalis nuchae;;• Group B: subjects with an uniform, black, professionally placed tattoo.

Exclusion criteria

• Known sensitivity to any components of the test materials;;• Pregnant or breast-feeding women;;• Use of any other pain medication during past 24 hours prior to the laser treatment;;• Damaged skin at the designated treatment site;;• Blister formation and/or scar formation after test-treatment with standard laser settings;;• Any medical or psychiatric condition which, in the investigator*s opinion, would preclude the participant from adhering to the protocol or completing the study per protocol.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-02-2015
Enrollment:	30
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Emla
Generic name:	lidocain/prilocain
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Pliaglis
Generic name:	lidocain/tetracain
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	01-10-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	14-11-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-01-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	27-01-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	EUCTR2014-003610-86-NL
CCMO	NL50770.078.14