A Randomized Clinical Trial of Cutaneous Xylocaine Spray to Reduce Intravenous Cannulation Pain in Adults.

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Objective: Adequate analgesia during intravenous cannulation.Hypothesis: Xylocaine spray for the placement of an infusion decreases the pain score with two or more points in comparison to placebo spray.Studie questions:Primary: Has xylocaine spray...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON43874

Source
ToetsingOnline

Brief title
Cutaneous xylocaine spray versus placebo spray

Condition

- Other condition

Synonym
Pain

Health condition

Pijnstillend effect van cutaan aangebrachte xylocaine spray voor plaatsing van een infuus.

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: Onderzoekers

Intervention

Keyword: Intravenous cannulation, Lidocaïne spray, Pain, Xylocaine spray

Outcome measures

Primary outcome

Primary outcome: The pain score of the tested subjects during intravenous

cannulation

Secondary outcome

Secundary outcome(s):

- Complications or adverse reactions of xylocaine spray

- Influence of xylocaine spray in successfully placing an IV cannulation

- The degree of difficulty in successfully placing an IV cannulation

Study description

Background summary

EMLA plasters or cream (lidocaine and prilocaine) and Rapydan plasters or cream (lidocaine and tetracaine) are currently being used as a local anesthetic for the intravenous cannulation in children. The maximum effect of EMLA occurs after 1-2 hours. Rapydan works faster and has a maximum effect after 30 minutes. However, Rapydan plasters (5.35 euro) and cream (2 grams: 3.67 euros) are more expensive than EMLA patches (2.79 euro) and cream (2 grams: 1.73 euros). During an acute care for a child in the emergency department, these means for analgesia for intravenous cannulation is less suitable. Xylocaine Spray is used in the anesthesia of the mucosa during oral surgery. It has within 1-3 min a local anesthetic effect. It is relevant to know whether cutaneous use of xylocaine spray has a faster anesthetic effect than EMLA or Rapydan (cream or plasters), in order that children, during an acute care in

the emergency department, experience less pain during intravenous cannulation.

Study objective

Objective: Adequate analgesia during intravenous cannulation.

Hypothesis: Xylocaine spray for the placement of an infusion decreases the pain score with two or more points in comparison to placebo spray.

Studie questions:
Primary: Has xylocaine spray an analgesic effect during the insertion of an intravenous cannulation?

Secondary: Are there any side effects when using xylocaine spray? Does xylocaine spray affect the successful placement of an intravenous cannulation?

Study design

The enrolled subjects will get an intravenous cannulation in both elbows. The influence of the left or right-handedness is reduced by randomizing the arms of the subjects in the placebo group or xylocaine group. The subject will get before xylocaine spray is placed, the intervention-arm, one intravenous cannulation in one of the elbows, the other intravenous cannulation is placed in de other arm before placebo spray is placed, the control arm. The pain score during insertion of de cannulation, the incidence of adverse events and the success rate and degree of difficulty to place an intravenous cannulation. The subjects and the one who place the cannulations will be blinded to the treatment.

Intervention

See the note in the study design.

Study burden and risks

The enrolled subjects will get an intravenous cannulation in both elbows. An infection will be able to occur at the location of the insertion hole after removal of the intravenous cannulation.

Possible side effects of xylocaine or placebo spray could occur, for example, local allergic skin reactions.

Contacts

Public
Isala Klinieken

Dokter van Heesweg 2
Zwolle 8025AB
NL
Scientific
Isala Klinieken

Dokter van Heesweg 2
Zwolle 8025AB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Adults (aged 18 or older)
Signing of the informed consent paper

Exclusion criteria

Allergy for xylocaine
Pregnancy or breast-feeding
Peripheral neuropathy
Analgesics in the last 24 hours
Skin conditions (eczema, psoriasis, infection, or abrasions)
Difficulties in verbal communication

No intravenous access in both elbows possible (eg status after axillary dissection)

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-04-2016
Enrollment:	17
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Xylocaine spray
Generic name:	Lidocaïne spray
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	07-03-2016
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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	EUCTR2015-003915-39-NL
ClinicalTrials.gov	NCT02562144
CCMO	NL54811.075.15