

# 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...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	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, Lidocaine spray, Pain, Xylocaine spray

## Outcome measures

### Primary outcome

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

### Secondary outcome

Secondary 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.

Study 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 the other arm before placebo spray is placed, the control arm. The pain score during insertion of the 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

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### Scientific

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## 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:	Lidocaine 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