

# The use of local anesthetics in wounds

<b>Submission date</b> 14/03/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 26/03/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 29/01/2019	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

In the emergency department (ED) pain treatment in acute wounds is often accomplished by injection with a local anesthetic (LA), for example lidocaine. As this can be painful, topical application (application to the surface of the skin) could be a painless alternative. Several studies have already investigated commercially available preparations for this purpose, however, it is not known whether the use of lidocaine without any additives, such as adrenaline (to locally constrict the blood vessels) works to treat pain in wounds requiring wound treatment. The aim of this study is to investigate whether lidocaine hydrochloride soaked gauzes can be successfully used to provide pain relief in treatment of acute traumatic wounds.

### Who can participate?

Adults (at least 18) presenting in the emergency department with an acute wound.

### What does the study involve?

Patients with acute traumatic wounds presenting to the ED treated with a nursing protocol using lidocaine soaked gauzes are included in the study and are asked about their experiences regarding pain in the period before and during wound treatment.

### What are the possible benefits and risks of participating?

Benefits are that there will be more attention to the pain experienced by the patient. There are no risks involved besides the use of lidocaine gauzes, as this is standard practice.

### Where is the study run from?

Academic Medical Center, Amsterdam (Netherlands)

### When is the study starting and how long is it expected to run for?

October 2014 to December 2014

### Who is funding the study?

Investigator initiated and funded

### Who is the main contact?

Dr Milan Ridderikhof

# Contact information

## Type(s)

Scientific

## Contact name

Dr Milan Ridderikhof

## Contact details

Meibergdreef 9  
Amsterdam  
Netherlands  
1105 AZ

# Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

1.0

# Study information

## Scientific Title

Anaesthesia with topical lidocaine hydrochloride gauzes in acute traumatic wounds: an observational study

## Acronym

LIGA Study (Lidocaine Impregnated Gauzes in Acute wounds)

## Study objectives

Lidocaine hydrochloride 2% soaked gauzes can effectively be used in providing analgesia in treatment of acute traumatic wounds in adult patients in the ED

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Waiver number W14\_311#14.17.0374

As the study was purely an observational study (there was already a nursing protocol in use describing the use of lidocaine gauzes in acute wounds) the IRB decided the Medical Research Involving Human Subjects Act did not apply to the study protocol

## Study design

Observational case series in a single-center (in which a nursing protocol using lidocaine soaked gauzes is already in place)

**Primary study design**

Observational

**Secondary study design**

Case series

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

**Health condition(s) or problem(s) studied**

Adult patients with acute traumatic wounds presenting to the ED

**Interventions**

Application of lidocaine hydrochloride (2%) soaked gauze in the wound before wound treatment

**Intervention Type**

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Lidocaine hydrochloride 2%

**Primary outcome measure**

Need for additional infiltration anaesthesia: this was measured at moment of surgical wound treatment at the ED.

**Secondary outcome measures**

1. NRS pain scores measured just before surgical wound treatment and during surgical wound treatment (in case no additional infiltration anaesthesia was required)
2. Adverse events: measured during the complete ED presentation
3. Satisfaction: measured at the end of wound treatment

**Overall study start date**

01/10/2014

**Completion date**

01/12/2014

**Eligibility**

**Key inclusion criteria**

1. Age 18 years and older
2. Presentation to the ED with an acute traumatic wound
3. Received analgesic treatment with lidocaine soaked gauzes (according to nursing protocol)

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Convenience sample during 8 weeks

**Key exclusion criteria**

1. Age 80 years and older
2. Body weight < 50 kg
3. Known allergy for local anaesthetics
4. Clinical suspicion of nerve injury
5. Manchester Triage System (MTS) category orange or red
6. Wounds due to chemical or thermal injury

**Date of first enrolment**

01/10/2014

**Date of final enrolment**

01/12/2014

**Locations****Countries of recruitment**

Netherlands

**Study participating centre**

Academic Medical Center (Academisch Medisch Centrum)

Meibergdreef 9

Amsterdam

Netherlands

1105 AZ

**Sponsor information**

**Organisation**

Academic Medical Center (Academisch Medisch Centrum)

**Sponsor details**

Meibergdreef 9  
Amsterdam  
Netherlands  
1105 AZ

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/03t4gr691>

**Funder(s)****Funder type**

Not defined

**Funder Name**

Investigator initiated and funded

**Results and Publications****Publication and dissemination plan**

One article with the main results will be submitted to a medical peer reviewed journal

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Stored in repository

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/09/2016		Yes	No