

The use of local anesthetics in wounds

Submission date 14/03/2015	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 26/03/2015	Overall study status Completed	☐ Protocol
Last Edited 29/01/2019	Condition category Injury, Occupational Diseases, Poisoning	☐ Statistical analysis plan
		☒ Results
		☐ 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

Protocol serial number

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

Primary study design

Observational

Study design

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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)

ROR

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

Funder(s)**Funder type**

Not defined

Funder Name

Investigator initiated and funded

Results and Publications

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?
Results article	results	01/09/2016		Yes	No