A randomised clinical trial on the effectiveness of Emla and Rapydan for prevention of vena punction-induced pain in children.

Published: 28-03-2011
Last updated: 27-04-2024

To study whether a novel plaster (Rapydan) is more successfull in diminishing pain/ discomfort than the usual plaster (EMLA).

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON35993

Source
ToetsingOnline

Brief title
Pain perception after vena punction.

Condition

- Other condition

Synonym
Pain perception/ discomfort

Health condition

Pijnbeleving

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: Isala Klinieken en producent Ripidan pleister

Intervention

Keyword: Children, Discomfort, Pain perception, Vena punction

Outcome measures

Primary outcome

Pain score on "pain face-scale".

Secondary outcome

Redness, Swelling, Access to the vein.

Study description

Background summary

Sedative plasters are usually admitted, prior to vena punction (blood sampling) in young children. The purpose of sedative plasters is to prevent (severe) pain/ discomfort.

Study objective

To study whether a novel plaster (Rapydan) is more successfull in diminishing pain/ discomfort than the usual plaster (EMLA).

Study design

Randomised Clinical Trial

Study burden and risks

Potential allergic reaction.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Age 3 - 18

Exclusion criteria

Allergy for the contents of the plaster

Study design

Design

Study phase:	4
Study type:	Observational non invasive
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-03-2011
Enrollment:	200
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	EMLA
Generic name:	LIDOCAINE/PRILOCAINE
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	RAPIDAN
Generic name:	LIDOCAINE/TETRACAINE
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	28-03-2011
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	29-03-2011

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	EUCTR2011-000750-37-NL
CCMO	NL35711.075.11