Influence from topical application of Rapydan before blood sampling on routine clinical chemistry en hematology measurements.

Published: 08-10-2009
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Determine if Rapydan does influence routine clinical chemistry and hematology measurements

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

Summary

ID

NL-OMON33774

Source
ToetsingOnline

Brief title
Influence Rapydan on routine clinical chemistry measurements.

Condition

- Other condition

Synonym
pain

Health condition

Pijnbestrijding voorafgaand aan een venapunctie of aanleggen infuus

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Laboratorium Noord
Source(s) of monetary or material Support: Medisch LabNoord;Groningen

Intervention

Keyword: blood sampling, clinical chemistry measurements, hematology measurements, Rapydan

Outcome measures

Primary outcome

Routine Clinical Chemistry measurements differences

Secondary outcome

not present

Study description

Background summary

There is an increasing awareness of the importance of treating procedure-related pain. Patients undergoing vascular access procedures are often afraid of needles and the discomfort associated with injections. This type of pain and/or fear can be stressful to patients. For prevention of the pain associated with these procedures, the hospital is using Rapydan plasters. Rapydan consists out of two local anesthetics: lidocaine and tetracaïne. Rapydan produces topical anesthesia after an application time of 30 minutes and is used in Dutch Hospitals for pain relieve by venapunction and IV cannulation. The venous blood draining the anaesthetized skin contains a higher blood concentration of the local anesthetics than does venous blood in other parts of the body. Although the concentrations of the local anesthetics are low in patients with normal skin, the question is whether the presence of the local anesthetics which Rapydan contains might influence routine measurements in clinical chemistry and hematology

Study objective

Determine if Rapydan does influence routine clinical chemistry and hematology measurements

Study design

Observational study with invasive measurements

Study burden and risks

1 hour presence at the GP's Lab, Damsterdiep Groningen, receiving 2 venipunctures, 30 minutes application of Rapydan Patch. Reading study information and writing informed concent. Risk are as normal venipuncture and the risk of side effects of Rapydan Patch.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Healthy, not seriously ill, patient descision competent, not allergic for local anesthetics lidocain and tetracaïne

Exclusion criteria

younger than 20 and older than 60
Hypersensitivity to the active substances(lidocaine and tetracaïne, to sodium borate or to any of the other excipients. Hypersensitivity to local anaesthetics of the amide or ester type or to para-aminobenzoic acid (by-product in tetracaine metabolism). Patients using Class I antiarrhythmic medicinal products (such as quinidine, disopyramide, tocainide and mexiletine) and class III antiarrhythmic medicinal products (e.g. amiodarone) or other products containing local anaesthetic agents.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2009
Enrollment:	25
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	08-10-2009
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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
ClinicalTrials.gov	NCT00765934
CCMO	NL24080.099.08