INFLUENCE OF LIDOCAINE UPON CELLULAR COAGULATION: IN VITRO INVESTIGATIONS USING THE MULTI-PLATE® THROMBOCYTE AGGREGOMETER

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The aim of the present study is therefore to investigate the commonly used LA lidocaine in its ability to attenuate thrombocyte aggregation in vitro.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coagulopathies and bleeding diatheses (excl thrombocytopenic)
Study type	Interventional

Summary

ID

NL-OMON35331

Source
ToetsingOnline

Brief title
Lidocaine and MultiPlate in vitro

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)

Synonym
coagulation, Thrombocyte function

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: coagulation, in vitro, lidocaine, local anesthetic

Outcome measures

Primary outcome

The main study parameter is thrombocyte aggregation in vitro in the ASPItest of MultiPlate, expressed as Area under the Curve (AUC).

Secondary outcome

Secondary objectives of the study are results from three other complementary tests using MultiPlate, i.e. the TRAPtest and COLtest, which both test the potential of activation of thrombocytes, and the ADP-test, which tests for thrombocyte impairment via the ADP pathway (e.g., clopidogrel).

Study description

Background summary

Local anesthetics (LA) are widely used in regional anesthesia and multimodal pain management. LA may directly interact with the coagulation cascade at the plasmatic and cellular level. Evidence for this assumption comes from clinical trials and experimental studies. Platelet aggregation seems to be inhibited by amide-type LA. Potential mechanisms include the inhibition of alpha-granule release, inhibition of calcium-dependent coagulation processes, and the interaction with Thromboxane A2-mediated platelet aggregation, corresponding to a weak aspirin-like effect. However, some of these results were obtained in non-platelet cell lines, and more detailed mechanisms have not been described. Moreover, investigations using the novel diagnostic device, MultiPlate®, have not been carried out.

Study objective

The aim of the present study is therefore to investigate the commonly used LA lidocaine in its ability to attenuate thrombocyte aggregation in vitro.

Study design

In vitro experiments in whole blood collected from healthy volunteers.

Intervention

The only intervention in volunteers is the drawing of 12 ml of whole blood via venipuncture. Intervention will take place in vitro: Incubation will be performed with lidocaine at concentrations between 5 and 100 mcg/ml for 1 hour at 37 degrees Celsius, followed by MultiPlate measurements.

Study burden and risks

The only intervention is to draw 12 ml of blood from healthy volunteers. No intervention in volunteers takes place.

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 volunteers, aged 18-65, ASA status I.

Exclusion criteria

History of abnormal bleeding, ingestion of coagulation imparing drugs, pre-existing disease of heart, lungs, vessels, kidneys or liver.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-07-2012
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission

Review commission: METC Amsterdam UMC

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
CCMO	NL37869.018.11