Verification of the Laser optical rotational cell analyser (LoRRca)

Published: 18-05-2016
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Verification of functional tests with the LoRRca, a next generation ektacytometer, on red blood cells of healthy individuals with or without comorbidities/risk factors.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON43928

Source
ToetsingOnline

Brief title
VELOR

Condition

- Other condition
- Cardiac disorders, signs and symptoms NEC
- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
healthy volunteers with or without comorbidities or riskfactors, Normal (healthy) population

Health condition

normale populatie, en populatie met comorbiditeit of risicofactoren

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: RR Mechatronics

Intervention

Keyword: Ektacytometry, LoRRca, Red blood cell, Validation

Outcome measures

Primary outcome

Determination of reference values of the different functional tests the LoRRca

is able to perform, and the identification of comorbidities that can influence

test results of the LoRRca.

Secondary outcome

Not applicable

Study description

Background summary

Ektacytometry is a method which can be used to investigate red blood cell membrane disorders. Laser Optical Rotational Cell Analyser (LoRRca) is a next generation ektacytometer which can be used to measure different aspects of red blood cell (RBC) deformability. Examples are deformability and aggregation which can say something about the stability and rheology of RBCs.

Red blood cells have to be highly deformable as they need to be able to pass through microcappillairies at high shear rate*s. Surface/volume ratio, pH, osmolarity, viscosity and membrane structure can influence red blood cell deformability. Many disorders alter one or more of these parameters and therefor influence deformability and rheology.

Most research has been done with aggregation and deformability assays. Limited research has been done with other of the different modalities the LoRRca is able to perform. In particular, a new modality has very recently been developed, enabling the study of RBC deformability under changing levels of oxygenation.

In order to use this instrument a study must be done in order to determine reference values and confounders of these reference values.

Study objective

Verification of functional tests with the LoRRca, a next generation ektacytometer, on red blood cells of healthy individuals with or without comorbidities/risk factors.

Study design

Cross-sectional observational study

Study burden and risks

The study will investigate blood of (healthy) volunteers. If possible the venipuncture will be combined with a routine visit. Otherwise one venipuncture is needed. The subjects will not benefit from this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

* 55-65 years (10), 20-30 years (40) or neonates (10)
* 55-65 years old, smoker (*-1 pack a day) and no other comorbidities (10)
* 55-65 years old and one of the following comorbidities: hypertension (10) or diabetes mellitus (10)
* 20-30 years old and obese (BMI >30) (10)
* Be able to give informed consent

Exclusion criteria

* Suffering from a serious condition not mentioned above
* Fever at time of venepuncture
* Not able to give informed consent
* Heavy alcohol drinking (more than 4 units a day)

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL
Recruitment status: Will not start

Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO Date:	18-05-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	16-11-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL55333.041.15