Validation Reseach of Medimate Minilab, Multi Lab-chip 2017

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21824

Source
Nationaal Trial Register

Brief title
VRMMML2017

Health condition

manic deppresive illness, total parenteral nutrition

Sponsors and support

Primary sponsor: CE-Mate BV, Radboud Universitair Medisch Centrum, Diagnostiek voor U
Source(s) of monetary or material Support: CE-Mate BV

Intervention

Outcome measures

Primary outcome

The primary result will be a validated Medimate Minilab 2017 with a defined Total Error in mmol/l with a confidence interval of 95%..

Secondary outcome

Specific validation results per patient group.

Interference test results.

Selftest performance results.

Method Comparison results.

Limit of quantification results.

Study description

Background summary

This study is to validate the Total Error of the Medimate Minilab for Sodium, Potassium, Lithium and Creatinine analysis in blood and for Sodium, Potassium, Creatinine and Magnesium analysis in Urine

These validation studies will provide statistical information concerning the accuracy, precision and reliability of the measurement under varying circumstances.

During this validation study the precision, accuracy and reliability are validated for the different parameters. These evaluations are designed to prove the Minilab 2017 performance under normal and extreme conditions.

Study objective

To validate the Total Error of the Medimate Minilab for Sodium, Potassium,Lithium and Creatinine analysis in blood and for Sodium, Potassium, Creatinine and Magnesium analysis in Urine

Study design

not applicable

Intervention

Validation of a selftest in finger prick whole blood, venous whole blood, plasma and urine.

Contacts

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Eligibility criteria

Inclusion criteria

1. > 18 years;

2. The participant has to be able to speak and read Dutch;

3. Healthy volunteers

4. The participant has to be part of the targeted patient group

Exclusion criteria

1. Under 18

2. No speaking and writing capabilities in Dutch

Study design

Design

Study type: Observational non invasive

Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-11-2017
Enrollment:	1185
Type:	Anticipated

Ethics review

Positive opinion

Date:	08-11-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48752
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6629
NTR-old	NTR6806
CCMO	NL62392.044.17
OMON	NL-OMON48752

Study results

Summary results

Staal, S. et al., A versatile electrophoresis-based self-test platform.
ELECTROPHORESIS, 2015, 36: 712–721. doi: 10.1002/elps.201400428