Validation Reseach of Medimate Miniab, Multi Lab-chip 2017

Published: 28-09-2017
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The main objective is to define the self-test performance by means of the Total Error for the Medimate Minilab 2017 for the set of parameters.

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

Summary

ID

NL-OMON48752

Source
ToetsingOnline

Brief title
Validation Medimate Minilab 2017, VRMMML2017

Condition

- Other condition
- Electrolyte and fluid balance conditions
- Manic and bipolar mood disorders and disturbances

Synonym
manic deppresive illness, total parenteral nutrition

Health condition

zelftest diagnostiek bij verschillende patient populaties en medicate controle, patienten met totale parenterale voeding

Research involving
Human

Sponsors and support

Primary sponsor: CE-Mate B.V.
Source(s) of monetary or material Support: door de sponsor CE-Mate BV;mede gefinancierd door een Euregio subsidie CrossCare

Intervention

Keyword: Blood, lab on a chip, self test, urine

Outcome measures

Primary outcome

Estimation of the Total Error of different self test parameters including an

evaluation of the self test capability.

Secondary outcome

n.a.

Study description

Background summary

CE-Mate BV, with trade name Medimate, has developed a self-test for blood and urine parameters based on microchip electrophoresis. The Medimate Minilab 2017 release of the self-test needs to be validated for different parameters that can be measured at once.

Study objective

The main objective is to define the self-test performance by means of the Total Error for the Medimate Minilab 2017 for the set of parameters.

Study design

The study design is based on method comparison, precision and interference evaluations in combination with a lay user questionnaire.

Study burden and risks

Patient need to travel and venous and finger stick samples are taken for the

study.
No direct benefit. Benefit on long term possible by improved therapy.
No health risks are identified other then the standard risks identified with venous and finger stick sampling.

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

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

Under 18, no speaking and writing capabilities in Dutch

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-11-2017
Enrollment:	1184
Type:	Actual

Ethics review

Approved WMO Date:	28-09-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	19-10-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	31-07-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	

Date:	27-03-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	28-10-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 21824
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL62392.044.17
Other	nog niet bekend