Cobas b 101 CRP Performance Evaluation

Published: 22-06-2017
Last updated: 12-04-2024

Evaluation of the point of care CRP test

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Ancillary infectious topics
Study type	Observational invasive

Summary

ID

NL-OMON45337

Source
ToetsingOnline

Brief title
Cobas b 101 CRP Performance Evaluation

Condition

- Ancillary infectious topics

Synonym
blood infection parameters, infection

Research involving
Human

Sponsors and support

Primary sponsor: Roche Diagnostic International Ltd.
Source(s) of monetary or material Support: Roche Diagnostics international Ltd.

Intervention

Keyword: CRP, diagnostic, point of care

Outcome measures

Primary outcome

Analytical performance, reliability and robustness

Secondary outcome

Interference

Study description

Background summary

In current medical practice, the CRP test is taken by venous sampling and analysed in the laboratory. A new point of care CRP test is develloped that needs onlt capillary blood sampling.

Study objective

Evaluation of the point of care CRP test

Study design

Diagnostic cohort study

Study burden and risks

Blood sampling at a single occation, including 2 fingerpricks and 1 venous blood draw.

Contacts

Public
Roche Diagnostic International Ltd.

Forrenstrasse 2
Rotkreuz CH6343
CH
Scientific
Roche Diagnostic International Ltd.

Forrenstrasse 2
Rotkreuz CH6343
CH

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

> 18 years of age
clinical patients with (known) raised CRP levels, and/or
patients who requier blood sampling within standard care

Exclusion criteria

contra-indication for blood drawing
pregnancy
breast feeding

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-06-2017
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO

Date:	22-06-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL61250.100.17