Comparison between venous collected plasma by lab technician and home collected capillary plasma by patient with haertfailure with respect to sodium, potassium, urea, creatinin, albumin and NTproBNP: usefulness of myBLOxs portable centrifuge

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Study on the validity and usability of myBLOxs portbale centrifuge at home by patient with heartfailure. Validity is measured by comparing laboratory results from venous plasma with those from capillary plasma.

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

Summary

ID

NL-OMON34201

Source
ToetsingOnline

Brief title
myBLOxs-labtest bloedcentrifuge

Condition

- Other condition
- Heart failures

Synonym

capillary and venous blood collection, hartfailure

Health condition

het betreft geen specifieke aandoening, maar vergelijk van bloedafname methoden

Research involving
Human

Sponsors and support

Primary sponsor: Deventer Ziekenhuis
Source(s) of monetary or material Support: bijdrage van klinisch chemisch laboratorium DZ en SKB Winterswijk voor analyse en inzet personeel

Intervention

Keyword: bloodcentrifuge, finger-stick, haertfailure, home-bloodcollect

Outcome measures

Primary outcome

Quantitative values for sodium, potassium, urea, creatinin, albumin and

NTproBNP for both venous and capillarry plasma from 3 x 40 samples

Statistical correlation is estimated by Bland Altman plot and calculated by

intra-class correlation (ICC)

Secondary outcome

After a capillary blood collection the patient fills in a basic form, which

register the practicle experience with the use of the myBLOxs and the

experience with teh finger stick.

Study description

Background summary

Recently, Hessels+Grob bv has developed a portable bloodcentrifuge for centrifugation of capillary blood at home (home collect test). Dr Jan Hessels

is owner of Hessels+Grob bv, and as clinical chemist in the Deventer Hospital. This trial is carried out by dr Maarten Beinema (MD, head of laboratory for trombosis and hemostasis) en dr Pita Bruggink (MD, outpatient clinic for haertfailure). The laboratory tests are performed on the clinical chemical laboratory of the SKB Hospital Winterswijk (dr Hans van der Vuurst, clinical chemist).

Study objective

Study on the validity and usability of myBLOxs portbale centrifuge at home by patient with heartfailure. Validity is measured by comparing laboratory results from venous plasma with those from capillary plasma.

Study design

Comparative study, by which the laboratory results for sodium, potassium, urea, creatinin, albumin and NTproBNP from venous vs capillary plasma are compared with each other. Venous blood is collected at home by laboratory technician at the same time as the patient collect his/her own capillary blood (within 2 hours) .

Study burden and risks

There is no or only slight risk associated wtih a finger stick. For safety reasons we added disposable safety autolancets (Becton Dickinson)

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

Patient with haert failure and reduced ejection fraction (< 45 %) who has to visit the out-patient clinic with a two or three week periodicity because of medication control by haert failure specialist or cardiologist.
Patient has to be capable to perform finger stick blood collection from medical point of view

Exclusion criteria

Patient with NYHA class IV haert failure

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-01-2011
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	20-10-2010
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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	NL32358.075.10