Is blood taken from intraosseous cannulation usable for laboratory assays in the acute setting?

Published: 20-12-2010
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To assess the comparability of routine blood analysis from intraosseous cannulation and peripheral venous blood in the emergency setting.

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

Summary

ID

NL-OMON34033

Source
ToetsingOnline

Brief title
Laboratory assays on bonemarrow

Condition

- Other condition

Synonym
n.a.

Health condition

hemodynamisch instabiele patiënten op de SEH

Research involving
Human

Sponsors and support

Primary sponsor: Atrium Medisch Centrum
Source(s) of monetary or material Support: via het laboratoriumbudget.

Intervention

Keyword: Clinical chemistry, Haematology, Intraosseous cannulation

Outcome measures

Primary outcome

The main study parameter is the comparability of laboratory values (i.e. sodium, potassium, magnesium, calcium, glucose, lactate, albumin, creatinine, urea, alkalin phosphatase, γ-GT, LD, ALAT, ASAT, CK, TnT, CBC, PT and APTT))in blood samples obtained by intraosseal cannulation and peripheral venous access.

Secondary outcome

Is the preanalytical quality of the bone marrow material sufficient for laboratory analysis. Quality will be assessed by using parameters such as hemolysss, lipaemia and the presence of bone fragments. The endpoint is the number of rejecte samples .

Number and type of the complications that are related to the use of the intraosseous canulle in comparison to complications when using an intraveneous catheter.

Study description

Background summary

In the emergency setting the use of intraosseous cannulation and infusion is

becoming more widely used. In need of fast access it is a save method for gaining access to the vascular system to infuse drugs and fluids when access through the peripheral venous route is difficult or impossible. It is under debate whether blood taken from intraosseous cannulation can be used for blood analysis. It would be an enormous advantage to the patient in the acute setting if blood obtained from intraosseous cannulation could also be used for laboratory assays. Important laboratory results will be faster known and consequently treatment will be started in an earlier stage. However, there is currently no evidence that reliable and comparable to peripheral venous levels can be obtained in blood samples taken from intraosseous cannulation in the acute setting.

Study objective

To assess the comparability of routine blood analysis from intraosseous cannulation and peripheral venous blood in the emergency setting.

Study design

Non-therapeutic, prospective, descriptive study

Study burden and risks

The only deviation from the standard procedure is the earlier use of intraosseous cannulation. An intraosseous cannulation is regularly being used in critically ill patients for the infusion of fluids. The usage is even being recommended by European and American guidelines. Our research population is only one step away in receiving an intraosseous cannula using the standard protocols. The potential risk for patients in this study will be the use of the intraosseous cannula, which is generally regarded as a safe method. Complications that may occur include the release of bone and/or fat fragments in the circulation, fracture at the entrance site, local infections of the bone or skin, subcutaneous spill of infusion fluids and the compartment syndrome. Research has shown that these complications are rare. Reported incidence varies from 0.9% to 4.8%. Risk of complications are even less as has been described for (deep) venous catheters in which complications such as infection, arterial puncture, pneumothorax and thrombosis. In addition, insertion of such a catheter is more time consuming than that of an intraosseous canulla (2,3min vs. 9.9min). Moreover, change of success is much larger by using an intraosseous canulla.
Not inserting an intraosseous canulla could be a greater risk to the patient in case of an emergency, as fluids and/or medication cannot be administered on time, which could be potentially fatal. This justifies the minimal risk of using an intraoseous canulla. In some instances the infusion of fluids through an intraoseous canulla can be painful, which can easily be treated by using lidocain before infusion. However, most patients will be unconscious.

Patients in the study protocol will only endure minimal discomfort and risks for complications are minimal.

Contacts

Public
Atrium Medisch Centrum

postbus 4446
6401CX Heerlen
NL
Scientific
Atrium Medisch Centrum

postbus 4446
6401CX Heerlen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Age: 18-80 years
- Hemodynamic unstable patients in need of two vascular access routes.For example.:
o Trauma
o Shock
o Cardiac arrest / resuscitation
o Burnwounds.
o Etc.

Exclusion criteria

- Age: < 18 years or > 80 year
- Hemodynamic stable patients
- Fracture of the proximale tibia
- (Skin)infection of the proximale tibia

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):	16-05-2011
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	20-12-2010
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL33727.096.10