Alternative IntraOsseous Devices Randomised controlled trial comparing 3 intraosseous methods.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23528

Source
NTR

Brief title
AIOD

Health condition

severely injured patients

Sponsors and support

Primary sponsor: Medirisk
Source(s) of monetary or material Support: -

Intervention

Outcome measures

Primary outcome

Primary endpoint: aspiration of bone marrow upon succesfull placement of a bone needle.
Primary parameter is: time required for successful placement.

Secondary outcome

Secundary endpoint: complications of the bone needle used.
Secundary parameters are: complications, success rates, user friendliness, pain encountered by the patient.

Study description

Background summary

Both in emergency departments and in prehospital services effort is being done to find a fast entrance to the circulation. If an intravenous access is not possible or it takes too long, intraosseous infusion is a good alternative both in adults and children. In the last few years, a few new intraosseous needles had been developed. The aim of this study is to analyze the time required to obtain a successful intraosseous entrance using the Bone Injection-Gun, Jamshidi and/or FAST1 intraosseous needles. The inserted needles will be compared on time to successful placement, adverse events and complications. The data achieved will enable us to pinpoint the best of intraosseous devices that will subsequently replace the currently used screw-tipped bone needle.

Study objective

The aim of this study is to analyse whether or not it is possible to created a fast, reliable intraosseous entrance using the BIG and/or FAST bone needles, with less complications compared with the traditional bone needle Jamshidi.

Intervention

The intervention consists of the application of a randomized instraosseous needle.
1. In people = > 14 years: BIG vs FAST vs conventional bone needle;
2. In children 1> and < 14 jaar: BIG vs conventional bone needle.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients in acute life threatening situations, requiring assistance of a mobile medical team;
2. Intravasculair medical or fluid resuscitation is necessary and intravasculair access cannot be obtained after two attempts.

Exclusion criteria

1. Childeren under the age of 1 year;
2. Patients with suspected sternumanomaly (only FAST1).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-06-2006
Enrollment:	150

Type:	Actual

Ethics review

Positive opinion

Date:	17-07-2006
Application type:	First submission

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
NTR-new	NL722
NTR-old	NTR732
Other	: N/A
ISRCTN	ISRCTN85744812

Study results

Summary results

Hartholt KA, Van Lieshout EMM, Thies WC, Patka P, Schipper IB. Intraosseous devices: a randomized controlled trial comparing three intraosseous devices. Prehosp Emerg Care 2010;14(1)6-13.