Alternative IntraOsseous Infusion Randomised controlled trial comparing 3 intraosseous methods

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

Summary

ID

NL-OMON29822

Source
ToetsingOnline

Brief title
AIOT

Condition

- Other condition

Synonym
polytrauma

Health condition

Acute/Spoedeisende situaties, waarbij inbrengen van een intraveneus infuus essentieel, maar niet mogelijk is

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Traumacentrum Zuid West Nederland / Erasmus MC

Intervention

Keyword: bone-injection gun, FAST, intraosseous infusion, Jamshidi

Outcome measures

Primary outcome

Primary endpoint: aspiration of bone marrow upon 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

Within the Netherlands there is a well-established network of trauma care. In emergency situations outside the hospital ambulance teams provide help. Upon their request a mobile medical team (MMT) may assist. This is primarily the case in life-threatening situations that instantly require additional medical support.
In order to be able to provide adequate fluid resuscitation and to administer medication, generating access to the patients* circulation is a prerequisite prior to stabilizing the patient. The Gold standard for accessing the circulation is placing an intravenous infusion. In certain situations, however, this may not be possible. For instance in patients with hypothermia, patients in shock, but also in (small) children, achieving intravenous access may not be possible. The best alternative in such cases is the intraosseous bone needle. This is a hollow metal tube that is placed into the bone marrow of e.g. the lower limb. Upon proper placement of the bone needle, an infusion system will

be connected to it, providing a means to admit fluid and medication. These substances reach the vasculair circulation via the bone marrow, which itself is abundantly vascularized. The bone needle, also called intraosseous device, is applied both in adults and children.
The bone needle may be applied both in children as in adults. In adult, it may be hard to place the bone needle due to composition of the bone. In former times, a screw-tipped bone needle was used by the MMT to create an entry to the circulation. This device, however, has been taken from the market in 2005.
Several novel intraosseous methods have been developed in order to properly place bone needles. According to the suppliers these new methods are faster and easier compared with the conventional bone needle.
In the current study, different types of bone needles will be compared. These include a conventional needle (Jamshidi), the Bone Injection Gun (BIG) and the First Access for Shock and Trauma (FAST).

Study objective

Both in emergency departments and in prehospital services (ambulances and MMTs) effort is being done to find a fast alternative for the screw-tipped bone needle that has the least amount of risk and complications.
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 complication compared with the traditional bone needles. The data achieved will enable us to pinpoint the bets of intraosseous device that will subsequently replace the screw-tipped bone needle.
The outcome of the study will impact emergency care both within Emergency Departments as well as ambulances and MMTs.

Study design

In order to objectively compare the three different devices, a randomized study will be performed, using clinical results, complication rate, and user friendliness as outcome measures.
For adults, 3 types of devices will be used. The conventional bone needle will be applied by rotation and pressure. The second device, BIG, contains a pressurized spring, that "launches" the needle into the intramedullar space. The FAST also contains a pressurized spring, but has been developed for use at the sternum site only. As opposed to the other devices, the FAST cannot be used in small children. The other devices can be applied at multiple locations. A separate study in children will be performed, comparing the BIG and the conventional bone needle.
Based upon a power calculation it was decided to test 30 bone needles of each type (3 types in adults, 2 in children). This makes 150 in total.
Critical care nurses of the MMT will place the needles and will collect data such as time required for proper placement and complications encountered. All data will be processed at the Trauma Centre South West Netherlands.

Intervention

The intervention consists of the application of a randomized bone needle.
- In people >= 14 years: BIG vs FAST vs conventional bone needle.
- In children <= 13 jaar: BIG vs conventional bone needle.

Inclusion criteria:
Patients with suspected sternumanomaly; large skin defects, skin infection or fracture at the site of the insertion location; Two or more placed bone needles

Exclusion criteria:
Patients in acute life threatening situations, requiring assistance of a mobile medical team. These patients need to be reanimated, or placement of an intravenous infusion has been insuccessful in two attempts.

Study burden and risks

This examination will not encompass addition risks for the patients.
For the patient no additional testing will be done due to this study. The physician removing the bone needle will be asked to fill out a short questionnaire.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Patients in acute life threatening situations, requiring assistance of a mobile medical team. These patients need to be reanimated, or placement of an intravenous infusion has been insuccessful in two attempts.

Exclusion criteria

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Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-06-2006
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	15-06-2006
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL11888.078.06