

Alternative IntraOsseous Devices

Randomised controlled trial comparing 3 intraosseous methods.

Gepubliceerd: 17-07-2006 Laatste bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23528

Bron

NTR

Verkorte titel

AIOD

Aandoening

severely injured patients

Ondersteuning

Primaire sponsor: Medirisk

Overige ondersteuning: -

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blinding:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestopt

(Verwachte) startdatum: 21-06-2006
Aantal proefpersonen: 150
Type: Werkelijke startdatum

Ethische beoordeling

Positief advies
Datum: 17-07-2006
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL722
NTR-old	NTR732
Ander register	: N/A
ISRCTN	ISRCTN85744812

Resultaten

Samenvatting resultaten

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.