# Alternative Intra Osseous Devices: randomised controlled trial comparing three intraosseous methods

Submission date	Recruitment status	Prospectively registered
28/12/2006	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
28/12/2006	Completed	Results
Last Edited	Condition category	Individual participant data
07/03/2008	Injury, Occupational Diseases, Poisoning	Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

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#### Contact details

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# Additional identifiers

**Protocol serial number** N/A

# Study information

#### Scientific Title

## Acronym

**AIOD** 

## **Study objectives**

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.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approval received from the Medical Ethical review board, Erasmus Medical Centre, Rotterdam, The Netherlands. The approval was completed at 15th June 2006 with reference number MEC-2006-109.

## Study design

Randomised, controlled, parallel group, single blinded study

## Primary study design

Interventional

## Study type(s)

**Treatment** 

## Health condition(s) or problem(s) studied

Severe injury, life threatening

### **Interventions**

The intervention consists of the application of a randomised instraosseous needle:

- 1. In people over 14 years: BIG versus FAST versus conventional bone needle
- 2. In children more than one and less than 14 years: BIG versus conventional bone needle

## Intervention Type

Device

#### Phase

**Not Specified** 

## Primary outcome(s)

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

## Key secondary outcome(s))

Secondary endpoint: Complications encoured using an intraosseous device Secondary parameters:

1. Adverse events

- 2. Success rate (%)
- 3. User friendliness (Visual Analogue Scale [VAS])
- 4. Pain scored by the patient (VAS)

## Completion date

20/06/2008

# **Eligibility**

## Key inclusion criteria

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

## Participant type(s)

**Patient** 

## Healthy volunteers allowed

No

## Age group

Other

#### Sex

**Not Specified** 

## Key exclusion criteria

- 1. Children under the age of one year
- 2. Patients with suspected sternumanomaly (only FAST1)

## Date of first enrolment

21/06/2006

## Date of final enrolment

20/06/2008

## Locations

## Countries of recruitment

Netherlands

## Study participating centre Erasmus Medical Center

Rotterdam Netherlands 3000 CA

# Sponsor information

## Organisation

Erasmus Medical Center (The Netherlands)

## **ROR**

https://ror.org/018906e22

# Funder(s)

# Funder type

Other

## **Funder Name**

Medirisk (The Netherlands)

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration