

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

**Submission date**

28/12/2006

**Recruitment status**

No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**

28/12/2006

**Overall study status**

Completed

☐ Statistical analysis plan

☐ Results

**Last Edited**

07/03/2008

**Condition category**

Injury, Occupational Diseases, Poisoning

☐ Individual participant data

☐ 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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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

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 create 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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

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

Severe injury, life threatening

## Interventions

The intervention consists of the application of a randomised intraosseous 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 measure**

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

**Secondary outcome measures**

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)

**Overall study start date**

21/06/2006

**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

**Age group**

Other

**Sex**

Not Specified

**Target number of participants**

150

**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)

### Sponsor details

Trauma Center ZWN

P.O. Box 2040

Amsterdam

Netherlands

3000 CA

### Sponsor type

Hospital/treatment centre

### Website

<http://www.erasmusmc.nl/>

### ROR

<https://ror.org/018906e22>

## Funder(s)

### Funder type

Other

### Funder Name

Medirisk (The Netherlands)

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration