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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

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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 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

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 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 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