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

Submission date
28/12/2006

Recruitment status
No longer recruiting

Registration date
28/12/2006

Overall study status
Completed

Last Edited
07/03/2008

Condition category
Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

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