Continuous non-invasive finger blood pressure monitoring - replacement of invasive pressure?

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To determine the clinical feasibility and performance of continuous, non-invasive FAP recording by ABM100 as a replacement of intra-arterial pressure in adult patients. Specifically, a) magnitude of pressure gradient distortion of the FAP pulse...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON30299

Source
ToetsingOnline

Brief title
Non-invasive blood pressure

Condition

- Other condition

Synonym
none

Health condition

circulatie monitoring van patienten tijdens narcose

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Blood pressure, Monitoring, Non-invasive

Outcome measures

Primary outcome

- Offset of finger blood pressure measurement in comparison to intra-arterial

pressure

Secondary outcome

- easiness of finger cuff application (5 point scale)

Study description

Background summary

Continuous non-invasive measurement of finger arterial pressure (FAP) in humans was introduced both for research purposes and for clinical medicine. The Finapres device has been shown to provide a useful alternative for continuous intra-arterial measurement in a variety of situations specifically for research purposes. Thus far technical problems related to improper finger cuff wrapping and low plethysmogram with cold fingers have limited application of non-invasive pressure monitoring in clinical medicine. To fill this gap a new monitor ABM100 with better easy-to-use finger cuffs has been developed.

Study objective

To determine the clinical feasibility and performance of continuous, non-invasive FAP recording by ABM100 as a replacement of intra-arterial pressure in adult patients. Specifically, a) magnitude of pressure gradient distortion of the FAP pulse waveform, b) effects of vasoconstriction on pulse wave disparity, c) effects of reduction of left ventricular ejection period on IAP vs. FAP amplification; d) absolute level offset of systolic, diastolic and mean finger arterial pressures, e) loss of measurement time and f) easiness of

finger cuff application and device control are determined.

Study design

Open prospective study in 30 patients admitted to the AMC for elective surgery who are provided for with an arterial line for monitoring purposes during general anesthesia.

1) Informed consent
2) A finger cuff is applied to the mid-phalanx of the middle finger of the dominant arm; the pressure transducer and the finger cuff are positioned at heart level.
3) Continuous finger arterial and intrabrachial pressures are measured simultaneously. In the first minute of measurement the positions of the finger cuff and pressure transducer are checked for possible hydrostatic level errors and, if necessary, readjusted.

Study burden and risks

none

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- general anesthesia
- intra-arterial monitoring

Exclusion criteria

Serious symptomatic peripheral vascular disease.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2006
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission

Review commission: METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL14707.018.06