Validation of two oscillometric blood pressure devices for use in preeclampsia

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Validation of Microlife 3BTO-A and OMRON for blood pressure measurement in women with moderate to sever preeclampsia.

Ethical review	Approved WMO
Status	Pending
Health condition type	Maternal complications of pregnancy
Study type	Observational non invasive

Summary

ID

NL-OMON29910

Source
ToetsingOnline

Brief title
Validation of blood pressure devices in preeclampsia

Condition

- Maternal complications of pregnancy

Synonym
preeclampsia. toxaemia of pregnancy

Research involving
Human

Sponsors and support

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

Intervention

Keyword: hypertension, oscillometry, preeclampsia

Outcome measures

Primary outcome

For each measurement pair the absolute value of the difference [test device] - [mean investigators auscultatory measurement] is calculated.

Each measurement pair is graded as A: Difference within 5 mmHg , B: difference within 10 mmHg and C: difference within 15 mmHg.

Depending on the number of readings that fall between pre-specified limits the device is approved yes or no. The International Protocol specifies that 33 patients are necessary for validation.

If the Microlife 3BTO-A and / or the OMRON meet the requirements of the International Protocol than use of these devices for blood pressure measurement can be recommended in women with moderate to severe preeclampsia. If requirements are not met than these devices should not be used to diagnose preeclampsia or to initiate treatment or adjust treatment in women with preeclampsia.

Secondary outcome

nvt

Study description

Background summary

Gestational hypertension is on of the most common medical disorder in pregnancy and occurs in 10-12% of all pregnancies. Accurate measurement of blood pressure is essential in prenatal care for risk assessment of pregnant women and the diagnosis of pregnancy induced hypertension and preeclampsia.
The auscultatory technique with a mercury sphygmomanometer is considered the method of choice, using the first and fifth phases of Korotkoff sounds. [1]

However, there is increasing evidence that this procedure may lead to misclassification due to patient related, investigator related and device related factors. Automatic readings may overcome these disadvantages. A number of automatic devices have been validated in pregnant women. Although the majority of these devices perform well during normal pregnancy, differences between automatic reading and auscultatory measurement were large and unpredictable with most devices in women with preeclampsia.[3-5] Only two automatic devices (Omron MIT and Microlife 3BTO-A) have demonstrated sufficient accuracy for use in women with preeclampsia. [6,7] However, most women in these studies had only moderately elevated blood pressure and concern regarding the accuracy at higher blood pressure levels remains. Accuracy at higher levels in pregnancy is of great importance as medical treatment in pregnancy is generally considered at higher blood pressure levels than in non-pregnant individuals. We therefore decided to validate both Microlife 3BTO-A and OMRON in women with moderate to sever preeclampsia

Study objective

Validation of Microlife 3BTO-A and OMRON for blood pressure measurement in women with moderate to sever preeclampsia.

Study design

The validation procedure will be performed according to the international protocol for validation of blood pressure devices in adults. [2]. Alternate auscultatory and automatic readings of systolic and diastolic blood pressure will be performed. The auscultatory measurements will be performed by two researchers. The mean value of each pair of investigator measurements will be calculated. In total, 9 auscultatory and 8 automatic blood pressure readings will be obtained. The first measurement set of each run is discarded from analysis.

Study burden and risks

The repeated blood pressure measurements will give some discomfort to the right arm of the patient. There is no risk involved for the baby or for the mother*s health.

References

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2. O'Brien E, Pickering T, Asmar R, Myers M, Parati G, Staessen J et

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3. Shennan AH, Halligan AW. Korotkoff Sounds. Blood Press Monit. 1996;1:495.
4. Koenen SV, Franx A, Oosting H, Bonsel GJ, Bruinse HW, Visser HA. Within-subject variability of differences between conventional and automated blood pressure measurements in pregnancy. Eur.J.Obstet.Gynecol.Reprod.Biol. 1998;80:79-84.
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6. Golara M, Benedict A, Jones C, Randhawa M, Poston L, Shennan AH. Inflationary oscillometry provides accurate measurement of blood pressure in pre-eclampsia. BJOG. 2002;109:1143-47.
7. Reinders A, Cuckson AC, Lee JT, Shennan AH. An accurate automated blood pressure device for use in pregnancy and pre-eclampsia: the Microlife 3BTO-A. BJOG. 2005;112:915-20.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
22660 1100DD Amsterdam
Nederland
Scientific
Academisch Medisch Centrum

Meibergdreef 9
22660 1100DD Amsterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

hospital admission because of severe preeclampsia = blood pressure > 140/95 mmHg and proteinuria > 0.3 g/24 hours

Exclusion criteria

None

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2006
Enrollment:	33
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	NL11954.018.06