Using motion and orientation sensors for monitoring labour and delivery

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To study whether an existing sensor device containing motion/orientation sensors (SMM; Senior Mobility Monitor) can be used to observe progress of labour.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON38979

Source
ToetsingOnline

Brief title
SMM-trial

Condition

- Other condition

Synonym
nvt

Health condition

weeenregistratie tijdens bevalling

Research involving
Human

Sponsors and support

Primary sponsor: Philips Research
Source(s) of monetary or material Support: Philips,Philips Research

Intervention

Keyword: external monitoring, obese population, uterine contractions registration

Outcome measures

Primary outcome

Main study parameters/endpoints: Aim of pilot study: To prove that the new SMM sensor detect contraction, especially in the obese population at least similair to the conventional TDM. Aim of the validation studie: To prove that the new SMM sensor will detect contraction, especially in the obese population at least similair to the golden standard IUP sensor.

Secondary outcome

see above

Study description

Background summary

Uterine contractions (during labour) can be visualised by a non-invasive tocodynamometer (TDM) or intra-uterine pressure sensor (IUP). The latter is an invasive procedure and does not reduce pregnancy outcome. External monitoring has, however, its limitations, especially in obesese patients. Furthermore, current non-invasive tocodynamometry cannot register the contration force. A better external registration of uterine contraction force in normal and especially obese patients should enhance the treatment of labouring women

Study objective

To study whether an existing sensor device containing motion/orientation sensors (SMM; Senior Mobility Monitor) can be used to observe progress of labour.

Study design

Prospective pilot and validation study
Intervention: Simultanous registration of progress of labour with a new

(CE-approved) external motion/orientation sensor (SMM) and the conventional external tocodynamometer (TDM, pilot study) and simultanous registration with an intra-uterine pressure device (IUP, validation study)

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Both conventional methods, IUP and TDM are used in common obstetrical practice. There is a small additional risk in using an IUP catheter compare to external monitoring. The SMM sensor is either attached to the extrernal TDM or in case of IUP sensor use placed in the same manner as the TDM and will therefore not lead to extra burden for the participants.

Contacts

Public
Philips Research

High Tech Campus 34
Eindhoven 5656 AE
NL
Scientific
Philips Research

High Tech Campus 34
Eindhoven 5656 AE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Singleton pregnancy
term pregnancy (gestational age at least 37 weeks
maternal age above 18 yeard at moment of inclusion

Exclusion criteria

plannend Caesarean Section
HELLP-syndrome
Severe intra uterine growth restriction in which induction of labour is indicated
known congenital anomalies

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2014
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	SMM device
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	18-12-2013
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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	NL46211.099.13