The intra uterine pressure catheter, the best way to messure uterine contractions?
A comparison of the intra uterine pressure catheter and the abdominal uterine pressure measurement during labor

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The objective of this study is to find out is the way contractions are maesurent during labor are of any influence on the lenght and the way women deliver. It also looks if there is any influence on neonatal outcome.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Maternal complications of labour and delivery
Study type	Observational invasive

Summary

ID

NL-OMON30600

Source
ToetsingOnline

Brief title
How to measure contractions during labor, intra uterine or abdominal?

Condition

- Maternal complications of labour and delivery

Synonym
strenght of contractions

Research involving
Human

Sponsors and support

Primary sponsor: Reinier de Graaf Groep
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: contractionregistration during labor, intra uterine pressure catheter

Outcome measures

Primary outcome

During of labor:

THe moment of rupturing of the membranes, or the start of dilation with

contractions needs to be noted, the time being meassured starts from first

vaginal examination till the birth of the child.

Interventions during labor:

- augmentation

- Sedation (pethidine)

- Epidural analgesie

- MBO (micro blood resaerch)

Outcome labor:

- Episiotomy

- Artificial births (splits on indications no progress and fetal stress)

- Sectio caesarea

Outcome neonatal:

- Apgar scores after 1, 5 en 10 minuten

- pH and BE from umbilicalcord blood

There will by looked at parae , etnicis and age, after the trial this will be corrected.

The groups are split in the intra uterine pressure catheter and the external meassurement. These two will be compared.

From the moment the women is randomized, she stays in the group she started. Independendly from interventions during the delivery. This means that a part of the women gets a intra uterine pressure cathter aldo they where primairy not in that group. This can happen when:

- There is not enough progress

- need for epidural

- suspicion of fetal stress

- inadequate external contractions registration

Secondary outcome

no secondary parameters

Study description

Background summary

When there is, during labor the need to have more information about the contractions the CTG (Cardio-Toco-Graphy) is being used. It registrates the fetal hartrate and the frequenty and during of contractions. This registration is extarnal. During labor it's possible to use an internal pressure catheter to meassure the contractions. This one will also meassure the strenght of the contractions. The only indications to use a pressure catheter is when there is a doubt about the strenght of the contraction , the fetal condition, or when the external registration is not adequate.

In the Netherlands all different hospitals use the pressure catheter with different guidelines. The Dutch Union of Gynaecology and Obstetrics is only advising to use the catheter when inducing labor ore while using augmentation. This is not evidence based. Where complications are known, there is no reluctance in the use of the catheter.

All studies that have been done, are comparing the use of the pressure catheter while labor in induced or augmention is used. The studies don't give a differance in outcome in during of labor, nummer of sectio ceasarion, use of augmentation and neonatal oucome (Chia 1993, Chua 1994). The thought that an intra uterine pressure catheter can avoid uterus ruptures is also not evidence based (Devoe 1992, Rodriquez 1989).

The use of the catheter is not withouth complications. There are different case reports that tells about infections and perforations af placentae, uterus en fetal vessels (Handwerker 1985 ,Lind 1999, Nuttall 1978). The percentages are low, so there are no figures about the risk of the use.

When there is no evidence that the use of something that brings some complications, there should be looked for evidence to use or not to use..

Study objective

The objective of this study is to find out is the way contractions are maesurent during labor are of any influence on the lenght and the way women deliver. It also looks if there is any influence on neonatal outcome.

Study design

A prospective, rondomized trial in the deliveryrooms of the Reinier de Graaf Gasthuis in Delft, The Netherlands. In each side of the trial there will be 50 women. It's a pilot study.

The trial is during labor. Patients will be screened when entering the delivery room for the inclusion criteria. The will get the informationletter and asked to sign if the agree to particepate in the trial. Clinical midwifes and residents will be in charge of the deliveries.

After the women agreed the will berondomized, and get a pressure catheter, or not. After that the CTG is being used as always, and the women will get normal care.

The midwife or resident keeps notes of the vaginal examinations. She writes down the personal number of the woman, so notes and outcome is easely found in the omputer.

Study burden and risks

The use of the catheter is not withouth complications. There are different case reports that tells about infections and perforations af placentae, uterus en fetal vessels (Handwerker 1985 ,Lind 1999, Nuttall 1978). The percentages are low, so there are no figures about the risk of the use. The burden is low, it gives more space to move than the external registration.

The use of external registration of contractions is without any risk

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

-The women have to be in active labor. (The midwife or resident is the judge of that and has to decide that she's going to deliver)
- spontaneous contractions (There's no primairy induction, and there has to be an expectacion of normal delivery)
- The patient is high risk, but the indication has nothing to do with the progression of labor.
- The patients are Aterme. Between the 37 and 42 weeks
-there has to be a minimal of 2 centimeters dilation (with less dilation it's impossible to place the catheter)

Exclusion criteria

-Take overs from low risk groups with indications:
*dilations with not enough progress (in need of augmentation)
*request epidural
*all indications witch are not during the stage of dilation
- induction af labor
-primairy oxytocin augmention
- Intra uterine infections
-intra uterine fetal death
- breech
- twin pregnancies
- maternal age < 18 years
- Hepatitis B cariers, or HIV infected women
- contra indications for amniotomy

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-05-2007
Enrollment:	500
Type:	Actual

Medical products/devices used

Generic name:	intra uterine pressure catheter
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	10-05-2007
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL15757.098.07