Benefit vs. Risks of Electronic Fetal Monitoring: - thoughts from Clinicians Perspective

LMU Frauenklinik | 14.03.2023 | Teresa Starrach, Uwe Hasbargen, Martin Daumer
One Year ago........

First experience with fetal home monitoring

Clinical Obstetrics, Gynecology and Reproductive Medicine

Case Report

ISSN: 2059-4828

Telemedical monitoring of a high-risk pregnancy with placental cyst in times of Corona: A case report

T. Starrach 1, M Daumer 1, A Hesse 1, M Rudelius 1, F Pfaller 1, J Kappeler 1, A Huber 1, C Häbener 1, S Mahner 1 and U Hasbargen 1

1Department of Obstetrics and Gynecology, University Hospital, LMU Munich
2Department of Pathology, University Hospital, LMU Munich
Division of Neonatology, Dr. V. Hauner Children’s Hospital and Perinatal Center Munich, LMU Munich

Prenatal Diagnostics Practice and DEGUM II, Munich
Objective

- Close monitoring of pregnant women during and after SARS-CoV-2 infection
- Reduction of clinic visits by infectious patients to protect other pregnant women and clinic staff

Inclusion criteria

- Acute or resolved SARS-CoV2 infection during pregnancy
- ≥24+0 weeks of pregnancy

Exclusion criteria

- Twin pregnancy
- High-grade obesity
- Language barrier
Planned study – first idea
Fetal home monitoring in pregnant women with SARS-CoV-2 infection

Objective
- Close monitoring of pregnant women during and after SARS-CoV-2 infection
- Reduction of clinic visits by infectious patients to protect other pregnant women and clinic staff

study plan

Trium mobile fleet contract

- How is it ensured that every CTG is seen by clinic staff in real time?
- Who is responsible if the pregnant woman writes a CTG outside the agreed time window?
The long road to starting a study

First idea:
Fetal home monitoring in pregnant women with SARS-CoV-2 infection

02/2022

09/2022

03/2022

first draft of a study plan

Corona becomes less important:
An other draft of the study plan

Trium mobile fleet contract
Increased risks in the 3rd trimester

- Post-term pregnancy
- Maternal age > 40
- Hypertension
- Preeclampsia
- Gestational diabetes
- Status after still birth
- ....

Prevention of premature delivery/preterm birth

Avoidance of complications and intrauterine death

Close monitoring

Many clinic or doctor visits
Telemedical monitoring of high-risk pregnant women to reduce hospital visits

Study Design

Inclusion criterion:

• Need for more closely monitored care than provided by maternity guidelines
• ≥18 years
• ≥24 weeks of gestation

Exclusion criterion:

• Twin pregnancy
• Language barrier
• Pathological CTG at study inclusion
• Indication for delivery

Randomization into 2 groups:
home-monitoring versus controls in the clinic
Primary objective:
Does pregnancy monitoring at home using Trium mobile fleet have the same quality as controls in the clinic?

Secondary objectives:
- What is the patient satisfaction with telemedical pregnancy monitoring?
- Does telemedical monitoring have a positive effect on the outcome of pregnancy?
- Are CTG datasets applicable to the development and testing of AI or machine learning (ML)-based applications?
- Will there be a reduction in the number of staff required?
Sample size calculation/power analysis

The histograms show the individual probability of whether CTG recording at home is successful.

With Var(bi)=1 the majority of pregnant women have a success rate > 0.5
With Var(bi)=2 there are also some who almost never succeed in producing an evaluable CTG.

<table>
<thead>
<tr>
<th>N</th>
<th>Power</th>
<th>Type-1-Fehler</th>
</tr>
</thead>
<tbody>
<tr>
<td>74</td>
<td>0.7950</td>
<td>0.0514</td>
</tr>
<tr>
<td>75</td>
<td>0.8048</td>
<td>0.0510</td>
</tr>
</tbody>
</table>
The long road to starting a study

02/2022

First idea:
Fetal home monitoring in pregnant women with SARS-CoV-2 infection

first draft of a study plan

09/2022

Second plan:
Telemedical monitoring of high-risk pregnant women to reduce hospital visits

Trium mobile fleet contract

Corona becomes less important:
An other draft of the study plan

Veto of the data protection commissioner

03/2022

Sampe size calculation

Agreement on the processing of personal data in the context of commissioned processing according to Article 28 DSGVO

Ethics statement

Start of study
Current case

- 36-year-old pregnant woman
- Premature rupture of membranes at 30+0 weeks of pregnancy
- Antenatal steroid prophylaxis
- Currently 34+6 weeks of pregnancy
- CTG home monitoring
- Blood draw at home by patient's husband (physician)
- 1x/week check-up in the clinic with ultrasound and vaginal smear test
Thank you for your attention!

teresa.starrach@med.uni-muenchen.de