HOspital care versus TELemonitoring in high risk pregnancy: the HOTEL trial

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To test telemonitoring with wireless CTG and blood pressure devices as a novel obstetric care strategy compared to hospital admittance in high risk pregnancies who require daily monitoring. Primary outcome is safety of pregnancy outcome measured by...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Maternal complications of pregnancy
Study type	Interventional

Summary

ID

NL-OMON47643

Source
ToetsingOnline

Brief title
HOTEL trial

Condition

- Maternal complications of pregnancy

Synonym
intrauterine growth retardation, preeclampsia

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,Stichting Achmea Gezondsheidszorg; Telenatal BV,Telenatal BV

Intervention

Keyword: fetal monitoring, pregnancy, telemedicine, telemonitoring

Outcome measures

Primary outcome

patient safety; composite of perinatal outcome is defined as perinatal

mortality, a 5-minute Apgar score below 7 and/or an arterial pH below 7,05,

maternal morbidity (such as eclampsia, HELLP syndrome, tromboembolic events),

NICU admission of the newborn and emergency caesarean section.

Secondary outcome

Patient satisfaction, quality of life and cost effectiveness will be assessed

using validated questionnaires and one self developed survey to look for

preferences for the new strategy will be developed

Study description

Background summary

Pregnancies with an increased risk of maternal or fetal complications often require long-term hospital admission. Innovative use of portable and wireless cardiotocography and blood pressure devices can be used for telemonitoring of high risk pregnancies. There are a number of advantages of telemonitoring for patients, health care providers, and insurance companies. In consultation with her own doctor or midwife, the high risk pregnancy patient will have more autonomy over her time and she will receive more feedback about vital functions.

Study objective

To test telemonitoring with wireless CTG and blood pressure devices as a novel obstetric care strategy compared to hospital admittance in high risk pregnancies who require daily monitoring. Primary outcome is safety of pregnancy outcome measured by perinatal mortality and morbidity. Secondary

objectives are patient satisfaction, quality of life and cost effectiveness.

Study design

Multicentre randomized controlled clinical trial; non-inferiority

Intervention

Randomisation will take place between traditional hospital admittance or telemonitoring for daily monitoring of maternal and fetal parameters. In telemonitoring pregnant women will make use of the Sense4Baby CTG registration device and Microlife blood pressure monitor and will have daily telephone calls with an obstetric health care professional in the hospital. Weekly outpatient visits will be planned for real-time contact and ultrasound assessment, blood sampling or urinary analysis if necessary.

Study burden and risks

Structural risk analysis is associated with moderate risk for randomized patients.
Patients can only be randomised when they meet strict inclusion criteria on knowledge of Dutch or English language and the understanding of the devices. Patients will be clearly instructed to perform measurement with all devices. They can make contact with health care professionals 24 hours per day if any physical complaints or questions arise. They should always get in touch before they perform measurement outside their treatment plan. If the patient does not understand the devices or the treatment plan, telemonitoring can be changed into clinical admission. These measures have proven our telemonitoring strategy before to be very effective, safe and patient friendly. In our hospital we already work with the devices for telemonitoring since 2014 and during these years no adverse advents occurred. This study however is powered on safety and we should therefor be careful not to take any conclusion too fast.
Possible risks include deterioration of maternal or fetal condition at home, e.g. rise in hypertension, physical complaints, non-reassuring CTG. These symptoms should be reported to the midwife or doctor in time to evaluate the condition in the hospital. If there is a patient delay or doctor*s delay (for example when the non-reassuring CTG has not been reviewed in time) quick transportation to the hospital may be needed, possibly with ambulance and paramedical help. Stablisation of hypertension with intravenous medication in clinical setting and induction of labour of caesarean section may be needed. However, this clinical decline cannot be prevented and can happen on ward as well as at home.
Possible benefits include the possibility to stay at home with all of its advantages. Women with experience in pregnancy telemonitoring reported relief about sleeping at home, better food, seeing partners and first child(s) more often and good feeling of security with at home monitoring and weekly

face-to-face visits. Main possible societal benefit is cost reduction of less clinical admissions of expensive ward beds while a considarable amounts of time is saved with measurements being done by the patient herself.

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

Necessity for hospital admittance for maternal or fetal surveillance because of one of the following: intrauterine growth retardation, preeclampsia, preterm premature rupture of membranes, recurrent reduced fetal movements, fetal anomaly (e.g. fetal gastroschisis) or prior perinatal demise in obstetric history.

Exclusion criteria

• Maternal age <18 years
• Pregnancy complications requiring intravenous therapeutics or obstetric intervention within 48 hours
• Blood pressure >160/110 mmHg
• Antepartum haemorrhage or signs of placental abruption
• CTG registration with abnormalities indicating fetal distress or hypoxia
• Multiple pregnancies
• Place of residence 30 minutes driving away from the nearest hospital
• Insufficient knowledge of Dutch or English language or impossibility to understand the training or instructions of the devices

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-12-2016
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO

Date:	21-09-2016
Application type:	First submission

Review commission:	METC NedMec
Approved WMO Date:	25-01-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	13-04-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	31-05-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	13-07-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	29-12-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	07-02-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	28-11-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	11-01-2019
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 28710
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL55884.041.16
OMON	NL-OMON28710