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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28710

Source
Nationaal Trial Register

Brief title
HOTEL

Health condition

- preeclampsia
- premature rupture of membranes
- intra uterine growth restriction (IUGR)
- high risk pregnancy
- telemedicine
- preeclampsie
- prematuur gebroken vliezen
- intrauteriene groeirestrictie
- ehealth
- foetale bewaking

Sponsors and support

Primary sponsor: UMC Utrecht
Source(s) of monetary or material Support: UMC Utrecht, Stichting Achmea Gezondheidszorg, Telenatal

Intervention

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

In this study we aim to study the effects of self-management at home in combination with telemedicine in high-risk pregnancies on safety, cost-effective and patient satisfaction. Pregnancies complicates with mild preeclampsia, intrauterine growth restriction, preterm rupture of membranes, recurrent reduced fetal movements, fetal anomalies requiring daily monitoring (e.g. gastroschisis) or fetal demise in obstetric history will be eligible for the study.

In this study we will train the use of the system to high-risk pregnant women teaching them how to handle the equipment. We expect that this facilitates the use of telemedicine at home irrespective of intelligence, technical skills, language barriers and socio-economic background.

In this study the following specific objectives will be addressed:
1) to determine whether this novel obstetric care strategy is as safe as the currently provided care during hospital admission;
2) to evaluate the feasibility and cost-effectiveness of telemedicine in high-risk pregnant women remaining at home;
3) to evaluate patient experience and satisfaction with a user-friendly surveillance system at home compared to currently provided hospital care for the same indication

Study objective

Self-management at home in combination with telemedicine in high-risk pregnancies is non-inferior compared to hospital admission regarding safety, cost-effectiveness and patient satisfaction.

Study design

inclusion 18 months

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 a wireless cardiotocograph registration device and home 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.

Contacts

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Eligibility criteria

Inclusion criteria

Necessity for hospital admittance for maternal or fetal surveillance because of one of the six following indications: intrauterine growth retardation, preeclampsia, preterm premature rupture of membranes, recurrent reduced fetal movements, fetal anomalies requiring daily monitoring (e.g. gastroschisis) or fetal 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 a 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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2016
Enrollment:	200
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	19-09-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47643
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5888
NTR-old	NTR6076
CCMO	NL55884.041.16
OMON	NL-OMON47643

Study results