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

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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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28710

Bron
NTR

Verkorte titel
HOTEL

Aandoening

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

Ondersteuning

Primaire sponsor: UMC Utrecht
Overige ondersteuning: UMC Utrecht, Stichting Achmea Gezondheidszorg, Telenatal

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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.

Onderzoeksopzet

inclusion 18 months

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-11-2016
Aantal proefpersonen:	200
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	19-09-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47643
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten