MOTHER trial: Maternal and Offspring outcomes after Treatment of HyperEmesis by Refeeding

Gepubliceerd: 02-10-2013 Laatst bijgewerkt: 15-05-2024

We hypothesize that enteral tube feeding is a more effective treatment for HG symptoms than intravenous rehydration and improves pregnancy outcome.

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

Samenvatting

ID

NL-OMON28457

Bron
NTR

Verkorte titel
MOTHER

Aandoening

Hyperemesis Gravidarum (HG)
Nausea and vomiting of pregnancy (NVP)
Zwangerschapsbraken
Intravenous rehydration
Intraveneuze rehydratie
Tube feeding
Sondevoeding
Neonatal outcomes
Neonatale uitkomsten
Maternal outcomes
Maternale uitkomsten
Long term outcomes
Langetermijn gevolgen
Quality of life
Kwaliteit van leven

Ondersteuning

Primaire sponsor: Prof. B.W. Mol, gynaecologist, Academic Medical Centre Amsterdam, University of Amsterdam, The Netherlands.
Overige ondersteuning: Prof. B.W. Mol, gynaecologist, Academic Medical Centre Amsterdam, University of Amsterdam, The Netherlands.
Foreest Medical School,

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary maternal outcome is the Pregnancy Unique Quantification of Emesis and nausea (PUQE) score one week after randomization.
The primary neonatal outcome is birth weight.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Hyperemesis gravidarum (HG), or intractable

vomiting during pregnancy, is the single most

frequent cause of hospital admission in early

pregnancy. HG has a major impact on maternal

quality of life and has repeatedly been associated

with poor pregnancy outcome such as low birth

weight. Currently, women with HG are admitted

to hospital for intravenous fluid replacement,

without receiving specific nutritional attention.

Nasogastric tube feeding is sometimes used as

last resort treatment . At present no randomised

trials on dietary or rehydration interventions have been performed. Small observational studies indicate that enteral tube feeding effectively may have the ability to treat dehydration and malnutrition and alleviate nausea and vomiting symptoms

Objective:
We aim to evaluate the effectiveness of early enteral tube feeding in addition to standard care on nausea and vomiting symptoms and pregnancy outcomes in HG patients

Study design:
The MOTHER trial is a multicentre open label randomised controlled trial (www.studies-obsgyn.nl/mother)

Study population:
Women ≥ 18 years and hospitalised for HG between 5+0 and 19+6 weeks gestation are eligible for participation

Intervention:
Participants will be randomly allocated to standard care with intravenous rehydration or early enteral tube feeding in addition to standard

care

Main study parameters:

The primary outcome will be neonatal birth

weight. Secondary outcomes will be the 24-hour

Pregnancy Unique Quantification of Emesis and

nausea score (PUQE-24), maternal weight gain,

dietary intake, duration of hospital stay, number

of readmissions, quality of life and side-effects.

Also gestational age at birth, placental weight,

umbilical cord plasma lipid concentration and

neonatal morbidity will be evaluated. Analysis will

be according to the intention to treat principle

Doel van het onderzoek

We hypothesize that enteral tube feeding is a more effective treatment for HG symptoms than intravenous rehydration and improves pregnancy outcome.

Onderzoeksopzet

Quality fo life will be measured at baseline with the following questionnaires:
Nausea and Vomiting of Pregnancy QoL (NVPQoL),
Hyperemesis Impact of Symptoms (HIS),
Hospital Anxiety and Depression Scale (HADS),
Symptoms Check List-90 (SCL-90),
Short Form-36 (SF-36),
European Quality of Life (EQ5D).
Patients fill in additional NVPQoL, HIS and HADS questionnaires 1 and 3 weeks after randomization.

Patients will record the PUQE (which consists of 3 questions), dietary intake and weight at weekly intervals until 20 weeks of gestation. If dietary intake has normalized from 15 weeks gestation onwards, this will no longer be recorded.

In addition they will complete questionnaires 6 weeks after delivery (SF-36, HADS, EQ5D) and 12 months after delivery (SF-36, HADS, EQ5D, SCL-90).

Onderzoeksproduct en/of interventie

Early enteral tube feeding, continued until sufficient oral intake versus intravenous rehydration (care as usual) in patients admitted because of hyperemesis gravidarum.

Contactpersonen

Publiek

Academic Medical Centre
Dept Obstetrics and Gynaecology
Room H4-213
PO Box 22700
B.W.J. Mol
Amsterdam 1105 DE
The Netherlands
+31 (0)20 5663919

Wetenschappelijk

Academic Medical Centre
Dept Obstetrics and Gynaecology
Room H4-213
PO Box 22700
B.W.J. Mol
Amsterdam 1105 DE
The Netherlands
+31 (0)20 5663919

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Gestational age between 5+0 and 19+6 weeks

Informed consent

Women with singleton or multiple pregnancy

Hospital admission because of hyperemesis gravidarum

First admission or readmission for HG

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Maternal age <18 years
Mola hydatidosa pregnancy
Non-vital pregnancy
Acute infection causing vomiting (acute appendicitis, pyelonephritis)
Contra-indication for enteral tube feeding (including oesophageal varices, allergies to compounds in enteral tube mix)
HIV infection

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	28-08-2013
Aantal proefpersonen:	120
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:	02-10-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 43713
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4024
NTR-old	NTR4197
CCMO	NL41011.018.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON43713

Resultaten

Samenvatting resultaten
Am J Clin Nutr. 2017 Sep;106(3):812-820. doi: 10.3945/ajcn.117.158931. Epub 2017 Aug 9.