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

No registrations found.

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

Summary

ID

NL-OMON28457

Source
Nationaal Trial Register

Brief title
MOTHER

Health condition

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

Sponsors and support

Primary sponsor: Prof. B.W. Mol, gynaecologist, Academic Medical Centre Amsterdam, University of Amsterdam, The Netherlands.
Source(s) of monetary or material Support: Prof. B.W. Mol, gynaecologist, Academic Medical Centre Amsterdam, University of Amsterdam, The Netherlands.
Foreest Medical School,

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Secondary outcomes are Pregnancy Unique Quantification of Emesis and nausea score (PUQE-24) one week after randomization,
maternal quality of life, duration of hospital stay and admission rates, maternal weight, ketonuria, neonatal morbidity, small for gestational age (SGA), prematurity and molecular outcomes in umbilical cord blood and placental tissue that relate to HG.

Study description

Background summary

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

Study objective

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

Study design

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).

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

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):	28-08-2013
Enrollment:	120
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion
Date: 02-10-2013
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 43713
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results

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