Misoprostol in the management of retained placenta, a safe alternative for manual removal? A randomised controlled trial.

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The use of 800 mcg of misoprostol prevents manual removal of the retained placenta in 80% of cases.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20129

Bron
NTR

Aandoening

Retained placenta

Ondersteuning

Primaire sponsor: Giel van Stralen
Overige ondersteuning: Self-financing

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Number of spontaneous delivered placentas;

2. Number of manual removals and amount of blood loss.

Toelichting onderzoek

Achtergrond van het onderzoek

Objective
To assess the effectiveness of misoprostol in the management of retained placenta. Will 800 micrograms of misoprostol orally reduce the need for manual removal under general anaesthesia and prove to be a safe alternative?
Method
All women with retained placenta after vaginal birth will be included in our study. Misoprostol 800 mcg or placebo will be administered. If a final attempt to deliver the placenta by controlled cord traction after 45 minutes fails, manual removal of the placenta will be performed. Side effects will be registered.
Sample size
Considering the results of our pilotstudy and historical data we want to include 100 women.
Outcome
Primary: number of spontaneous delivered placentas, number of manual removals and amount of blood loss. Secondary: interval between delivery of the baby and administration of misoprostol, interval between administration of misoprostol and delivery of the placenta, placenta captiva.

Doel van het onderzoek

The use of 800 mcg of misoprostol prevents manual removal of the retained placenta in 80% of cases.

Onderzoeksproduct en/of interventie

In case of retained placenta: administration of either 800 mcg of misoprostol or placebo 60 minutes after birth of the baby, in absence of postpartum haemorrhage

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. All women with at least 25 completed pregnancy weeks and retained placenta;
2. At least 18 years of age;
3. Master the Dutch language in word and script.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Excessive blood loss (>1000 ml) within 60 minutes after the delivery of the newborn;
2. Allergy for misoprostol or one of its components.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-08-2007

Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	25-06-2007
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL975
NTR-old	NTR1002
Ander register	:
ISRCTN	ISRCTN45330307

Resultaten