Comparing Two Medical Treatments for Early Pregnancy Failure.

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In EPF, the sequential combination of mifepristone with misoprostol is superior to the use of misoprostol alone in terms of complete evacuation of products of conception, patient satisfaction, complications, side effects and costs.

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

Samenvatting

ID

NL-OMON22735

Bron
NTR

Verkorte titel
Triple M Studie

Aandoening

Early pregnancy failure. Miskraam

Missed abortion.

Misoprostol

Mifepristone.

Ondersteuning

Primaire sponsor: Canisius Wilhelmina Ziekenhuis Nijmegen
Overige ondersteuning: Innovatiefonds Zorgverzekeringen” (project number: 3080 B15-191).
Canisius Wilhelmina Ziekenhuis (Nijmegen)
Radboudumc (Nijmegen)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Complete evacuation/ succesful treatment
Whether or not complete evacuation (total endometrial thickness <15 mm) has been acquired will be assessed 15-20 days after the initial treatment. If so, this will be considered a complete evacuation and thus successful treatment. If the total endometrial thickness is ≥ 15 mm, ultrasonography will be repeated six weeks after initial treatment. Once again, if the total endometrial thickness is <15 mm this will be considered as a complete evacuation and thus a successful treatment.

Toelichting onderzoek

Achtergrond van het onderzoek

This study will test the hypothesis that, in EPF, the sequential combination of mifepristone with misoprostol is superior to the use of misoprostol alone in terms of complete evacuation of products of conception (primary outcome), patient satisfaction, complications, side effects and costs (secondary outcomes). The trial will be performed multi-centred (hospitals), prospectively, two-armed, randomized, double-blinded and placebo-controlled.

Women with ultrasonographically confirmed EPF (6-14 weeks postmenstrual), managed expectantly for at least one week, can be included. Before medical treatment with misoprostol (two doses 400mcg (four hours apart), repeated after 24 hours if no tissue is lost), patients will be randomized to oral mifepristone (600mg) or oral placebo (identical in appearance). We aim to randomize 460 women in a 1:1 ratio, stratified by centre.

After six weeks, the primary endpoint, complete or incomplete evacuation, will be determined. An endometrial thickness <15mm (maximum anterior-posterior diameter) by ultrasonography and no evidence of retained products of conception using only the allocated therapy, is considered as successful treatment result. Secondary outcome measures are registered using the case report form, a patient diary and validated digital questionnaires.

Doel van het onderzoek

In EPF, the sequential combination of mifepristone with misoprostol is superior to the use of misoprostol alone in terms of complete evacuation of products of conception, patient satisfaction, complications, side effects and costs.

Onderzoeksopzet

Ultrasound will be performed 15-20 days after initial treatment. If treatment is not successful at that time another ultrasound wil be performed six weeks after initial treatment.

Onderzoeksproduct en/of interventie

Before medical treatment with misoprostol (two doses 400mcg (four hours apart), repeated after 24 hours if no tissue is lost), patients receive oral mifepristone (600mg).

The control arm receives an oral placebo.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

nclusion Criteria:

Early pregnancy failure, 6-14 weeks postmenstrual with

- a crown-rump length ≥ 6mm and no cardiac activity OR

- a crown-rump length <6mm and no fetal growth at least one week later OR

- a gestational sac with absent embryonic pole for at least one week.

• At least one week after diagnosis OR a discrepancy of at least one week between crown-rump length and calendar gestational age

• Intrauterine pregnancy

• Women aged above 18 years

• Hemodynamic stable patient

• No signs of infection

• No signs of incomplete abortion

• No contraindications for mifepristone or misoprostol

• No high risk of thrombosis

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patient does not meet inclusion criteria, discovered after randomization. Inability to give informed consent

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	13-06-2018
Aantal proefpersonen:	460
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:	03-07-2017
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	NL6366
NTR-old	NTR6550
Ander register	ABR nummer : 62449

Resultaten

Samenvatting resultaten

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