Comparing Two Medical Treatments for Early Pregnancy Failure.

No registrations found.

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

Summary

ID

NL-OMON22735

Source
NTR

Brief title
Triple M Studie

Health condition

Early pregnancy failure. Miskraam

Missed abortion.

Misoprostol

Mifepristone.

Sponsors and support

Primary sponsor: Canisius Wilhelmina Ziekenhuis Nijmegen
Source(s) of monetary or material Support: Innovatiefonds Zorgverzekeringen” (project number: 3080 B15-191).
Canisius Wilhelmina Ziekenhuis (Nijmegen)
Radboudumc (Nijmegen)

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

patient satisfaction, complications, side effects and costs.

Study description

Background summary

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.

Study objective

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.

Study design

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.

Intervention

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.

Contacts

Public
Canisius Wilhelmina Ziekenhuis / Radboud UMC
C.C. Hamel
Weg door Jonkerbos 100

Nijmegen 6532 SZ
The Netherlands
0031243658750
Scientific
Canisius Wilhelmina Ziekenhuis / Radboud UMC
C.C. Hamel
Weg door Jonkerbos 100

Nijmegen 6532 SZ
The Netherlands
0031243658750

Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-06-2018
Enrollment:	460
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	03-07-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6366
NTR-old	NTR6550
Other	ABR nummer : 62449

Study results

Summary results

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