Mifepristone and misoprostol versus misoprostol alone for uterine evacuation after early pregnancy failure: a pilot study

Published: 31-05-2016
Last updated: 19-03-2025

Th**is study will compare sequential mifepristone and misoprostol (*M&M*) treatment versus misoprostol treatment alone, which is currently the standard medical treatment in the Netherlands.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Abortions and stillbirth
Study type	Interventional

Summary

ID

NL-OMON43323

Source
ToetsingOnline

Brief title
M&M trial

Condition

- Abortions and stillbirth

Synonym
early pregnancy failure, miscarriage

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: Radboudumc;Canisius-Wilhelmina Ziekenhuis,Exelgyn

Intervention

Keyword: Early pregnancy failure, Medical treatment, Mifepristone, Misoprostol

Outcome measures

Primary outcome

The primary outcome will be complete evacuation of the products of conception from the uterus, which is determined by routinely ultrasonography six to nine days after treatment.

Secondary outcome

The secondary objectives are patient satisfaction, side effects and complications.

Study description

Background summary

Early pregnancy failure (EPF) is a common complication of pregnancy. Yearly in the Netherlands, 10.000 women with EPF do not abort spontaneously and do receive medical or surgical treatment in order to remove the products of conception from the uterus. For many years, surgical treatment (dilatation and curettage) has been the standard treatment. However, medical treatment is a safer and less expensive alternative. Misoprostol (synthetic prostaglandin E1 analogue) is used as standard medical treatment. Unfortunately, the current medical treatment with misoprostol only has a 54% complete evacuation rate without additional surgery. Medical treatment for EPF can most probably be improved. For other conditions, such as medical termination of vital pregnancy, the combination of mifepristone with misoprostol has been shown to be superior to the use of misoprostol alone. The superiority of the combination has also been demonstrated for induction of labour in case of fetal death after the first trimester. Therefore, it is reasonable to believe that, also for early pregnancy failure, mifepristone with misoprostol will be superior to misoprostol alone. Based on retrospective data in the Radboudumc Hospital (a pilot study) that are compatible with data from the literature, we expect a

complete evacuation rate of at least 67%. However, until now conclusive evidence is lacking. A randomized, double blind placebo-controlled trial is required to test the hypothesis that in early pregnancy failure the sequential combination of mifepristone with misoprostol is superior to the use of misoprostol alone.

Study objective

Th**is study will compare sequential mifepristone and misoprostol (*M&M*) treatment versus misoprostol treatment alone, which is currently the standard medical treatment in the Netherlands.

Study design

The trial will be conducted prospectively, two-armed, randomized, double-blinded and placebo-controlled.

Intervention

After randomization at day 1 :

- Mifepristone 600mg in the intervention group
- placebo in the control group

followed by the standard treatment with misoprostol : two doses of 400ug orally at day 3 and 4.

Study burden and risks

We intend to compare medical treatments that are already applied worldwide for several other indications. No additional physical examination is needed for this study, nor will extra blood be taken from the subjects. Study participants will receive information and will be asked to fill in questionnaires at three different time points. Participants are followed in an outpatient clinic; hospital admission is possible at all times. We do not expect additional risks or benefits.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Early pregnancy failure, 6-14 weeks postmenstrual with a
o Crown-rump length * 6mm and no cardiac activity OR
o Gestational sac without embryonic pole, confirmed by a second ultrasound at least one week later
* At least one week after diagnosis OR a discrepancy of at least one week between crown-rump length and calendar gestational age
* Intra-uterine 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 phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-10-2016
Enrollment:	40
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Cytotec
Generic name:	misoprostol
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Mifegyne
Generic name:	mifepristone
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	31-05-2016
Application type:	First submission

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	21-06-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 21883
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2013-001554-10-NL
CCMO	NL57892.091.16
OMON	NL-OMON21883

Study results

Date completed:	11-06-2017
Actual enrolment:	40

Summary results
Trial is onging in other countries