MisoREST: What should be done in women with an incomplete evacuation of the uterus after treatment with misoprostol for miscarriage?

No registrations found.

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

Summary

ID

NL-OMON28421

Source
NTR

Brief title
MisoREST

Health condition

misoprostol, incomplete evacuation, curettage, expectant management
misoprostol, zwangerschapsrest, curettage, expectatief beleid

Sponsors and support

Primary sponsor: AMC
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

Sonographic finding of empty uterus (max diameter of uterine contents < 10mm); 6 weeks after randomization.

Secondary outcome

1. Quality of Life (measured with SF-36 and HADS): baseline, 1-2 weeks, 4 weeks and 3 months after randomization;

2. Recovery specific Quality of Life: measured with RI-10 4 weeks after randomization, and EuroQol 3 months after randomization;

3. Number of out-of-protocol visits in the 3 months after randomization;

4. Numer of (re)interventions in the 3 months after randomization;

5. Pregnancy rates after 12 months.

Study description

Background summary

Objective of the MisoREST trial: To assess the effects of curettage versus expectant management in women with incomplete evacuation of the uterus after treatment with misoprostol for first trimester miscarriage.

Study objective

The primary study question is phrased as a non-inferiority hypothesis of expectant management versus curettage. Curettage is expected to lead to a higher proportion of patients succesfully treated, but we anticipate that women will prefer expectant management if the proportion of succes is not substantially lower.

Study design

Primary outcome (sonographic finding of empty uterus): 6 weeks.

Secondary outcomes:

1. Quality of life: baseline, 1-2 weeks, 4 weeks and 3 months;

2. Out-of-protocol visits: 3 months;

3. (Re)interventions: 3 months;

4. Pregnancy rates: 12 months.

Intervention

1. Curettage;

2. Expectant management.

Contacts

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Eligibility criteria

Inclusion criteria

1. First trimester miscarriage treated with misoprostol;

2. Sonographic evidence of remnant at follow-up 1-2 weeks after initial treatment.

Exclusion criteria

1. Age < 18 years;

2. Severe vaginal bleeding;

3. Severe abdominal pain;

4. Fever (> 38.0) or sepsis requiring antibiotic treatment and curettage;

5. Failed misoprostol-induced miscarriage: sonigraphic finding of intact gestational sac still in

situ.

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):	01-02-2012
Enrollment:	162
Type:	Actual

Ethics review

Positive opinion

Date:	27-02-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39356
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3166
NTR-old	NTR3310
CCMO	NL38637.018.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39356

Study results

Summary results
N/A