What should be done in women with an incomplete evacuation of the uterus after treatment with misoprostol for miscarriage? An analysis of costs and effects.

Published: 14-02-2012
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To assess costs and effects of curettage versus expectant management in women with incomplete evacuation of a miscarriage, as diagnosed with sonography, after misoprostol.

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

Summary

ID

NL-OMON39356

Source
ToetsingOnline

Brief title
MisoREST

Condition

- Abortions and stillbirth

Synonym
miscarriage, retained products of conception

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Cost-effectiveness, Miscarriage, Misoprostol, Vacuum evacation

Outcome measures

Primary outcome

The primary outcome is the success rate in reaching an empty uterus, as

substantiated by normal sonographic findings.

Secondary outcome

Secondary outcomes are Quality of Life scores assessed with the SF-36, the need

of additional treatments, complications, quality of recovery pain and costs.

Study description

Background summary

Recent studies have shown that in women with miscarriage misoprostol is a cost-effective alternative for immediate curettage. A problem with misoprostol is that after initial treatment, sonographic findings during follow-up frequently show incomplete evacuation of uterine contents, which often leads to additional interventions, i.e. suction curettage, thereby limiting the benefits of primary misoprostol treatment.

Study objective

To assess costs and effects of curettage versus expectant management in women with incomplete evacuation of a miscarriage, as diagnosed with sonography, after misoprostol.

Study design

Multicentre randomized clinical trial with a cost-effectiveness analysis

alongside it.

Intervention

Curettage versus expectant management.

Study burden and risks

Participants fill out questionnaires at five points in time, which will take them about 5 minutes every time. Furthermore, a fingerstick will be performed in order to determine Hb.

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

Patients with a miscarriage treated with misoprostol, and sonographic evidence of remnant of the miscarriage at the follow-up visit 7 days after initial treatment.

Exclusion criteria

Women aged below 18 years
Women with severe vaginal bleeding
Women with severe abdominal pain
Women with fever (> 38.0) or sepsis requiring antibiotic treatment and curettage,
Women with contraindications for curettage
Women with a failed misoprostol-induced miscarriage, as substantiated by the sonographic finding of an intact gestational sac still in situ.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-07-2012
Enrollment:	162
Type:	Actual

Ethics review

Approved WMO

Date:	14-02-2012

Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-05-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-06-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-06-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-07-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-07-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-03-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-04-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-05-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-06-2013

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-08-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-11-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-10-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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: 28421
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL38637.018.11
OMON	NL-OMON28421