

A comparison of vaginal misoprostol versus vaginal misoprostol and nitric oxide donor for termination of pregnancy at 13 to 29 weeks. A prospective randomised trial

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| Submission date 16/12/2002 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 16/12/2002 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 24/08/2009 | Condition category Pregnancy and Childbirth | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Study objectives

Not provided at time of registration.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration.

Study design

Randomised active controlled parallel group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Obstetrics and gynaecology

Interventions

After inclusion, patients will be randomised in two groups:

First Group (Risordan®): Misoprostol (200 µg) will be administered vaginally every 12 h. In addition, 20 mg isosorbide dinitrate Risordan® will be administered vaginally every 12 h.

Second Group (Controls): In this group, only misoprostol will be administered (200 µg every 12 h).

Principal participant variables:

1. Maternal age and parity
2. Gestational age
3. Induction to abortion interval
4. 48 h successful abortion rate
5. Mother satisfaction
6. Hospital stay (in hours)

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Isosorbide dinitrate (Risordan®), misoprostol

Primary outcome(s)

Not provided at time of registration.

Key secondary outcome(s)

Not provided at time of registration.

Completion date

30/04/2003

Eligibility

Key inclusion criteria

1. All patients requiring a termination of pregnancy between 13 and 29 weeks of gestation
2. No pregnancy induced hypertension
3. No pre-eclampsia
4. No vaginal bleeding
5. Cervix dilated less than 2 cm
6. No vaginal bleeding
7. At admission blood pressure: systolic >120 mmHg; diastolic >80 mmHg

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

01/04/2002

Date of final enrolment

30/04/2003

Locations

Countries of recruitment

Tunisia

Study participating centre

Maternité de Sousse

Sousse

Tunisia

4000

Sponsor information

Organisation

Farhat Hached University Teaching Hospital (Tunisia)

ROR

<https://ror.org/0059hys23>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

No external funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 01/12/2005 | | Yes | No |