ISRCTN44341343 https://doi.org/10.1186/ISRCTN44341343

# 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

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 16/12/2002 | No longer recruiting | [ ] Protocol |
| Registration date | Overall study status | [ ] Statistical analysis plan |
| 16/12/2002 | Completed | [X] Results |
| Last Edited | Condition category | [ ] Individual participant data |
| 24/08/2009 | Pregnancy and Childbirth | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr Samir Hidar

**Contact details**
Maternité de Sousse
CHU F Hached
Boulevard Med Karoui
Sousse
Tunisia
4000
+216 98404526
HIDAR.SAMIR@gnet.tn

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
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

**Secondary study design**
Randomised controlled trial

**Study setting(s)**
Hospital

**Study type(s)**
Treatment

**Participant information sheet**

**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 measure**
Not provided at time of registration.

**Secondary outcome measures**
Not provided at time of registration.

**Overall study start date**
01/04/2002

**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 then 2 cm
6. No vaginal bleeding
7. At admission blood pressure: systolic >120 mmHg; diastolic >80 mmHg

**Participant type(s)**
Patient

**Age group**
Adult

**Sex**
Female

**Target number of participants**
Added 24/08/09: 34 in Risordan® group (31 completed trial), 36 in control group (30 completed trial)

**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)

**Sponsor details**
Department of Obstetrics and Gynaecology
Boulevard M Karoui
Sousse
Tunisia
4000
+216 7322 9990

**Sponsor type**
Hospital/treatment centre

**Website**
http://www.chu-hached.rns.tn/en/index.htm

**ROR**
https://ror.org/0059hys23

## Funder(s)

**Funder type**
Hospital/treatment centre

### Funder Name
No external funding

## Results and Publications

### Publication and dissemination plan
Not provided at time of registration

### Intention to publish date

### 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 |