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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
16/12/2002

Registration date
16/12/2002

Last Edited
24/08/2009

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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

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.

Primary study design
Interventional

Study design
Randomised active controlled parallel group trial

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 then 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