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 No longer recruiting	Prospectively registered		
16/12/2002		☐ Protocol		
Registration date 16/12/2002	Overall study status Completed	Statistical analysis plan		
		[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

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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

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