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The use of extract of the roots of the South-African Uzara plant in the treatment of patients with primary dysmenorrhoea

Submission date	Recruitment status	[_] Prospectively registered
25/11/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
31/01/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/05/2015	Urological and Genital Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Comparative randomised cross-over study of the efficacy and safety of the extract of the roots of the South-African Uzara plant and ibuprofen in the treatment of patients with primary dysmenorrhoea

Study objectives
It is documented that the extract of the roots of the South-African Uzara plant (Uzara®) has an inhibitory action on the motility of smooth muscle organs through stimulation of the inhibitory sympathetic supply. This characteristic action is proved to affect the circular and longitudinal muscle of the whole intestinal tract, the urinary bladder, and the uterus. Hence, the use of Uzara® would inhbit painful uterine contraction and cramping pain in subjects with moderate to severe primary dysmenorrhoea.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics and Research Committee of Faculty of Medicine, Ain Shams University, September 2010.

Study design
Phase III prospective randomised comparative two-way cross-over assignment safety/efficacy pilot study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Primary dysmenorrhoea

Interventions
The subjects will be recruited from female students attending clinical classes in medicine (Faculty of Medicine) or nursing (High Institute of Nursery) at Ain Shams University Maternity Hospital. Sixty students having moderate or severe primary dysmenorrhoea and adhering to inclusion criteria will be recruited and a written consent will then be obtained before admission into the study.

Pre-treatment ultrasound screening will be performed to exclude any pelvic pathology. The case record form will be filled, including demographic information such as patient's age, parity, medical and surgical histories, and indications for the surgery. Then, historical data will be collected including measurement of severity of dysmenorrhoea, pain assessment by pain scales: visual analogue scale (VAS), self-reported and self-rated verbal scale, and multidimensional scoring system (MDS). Visual Analogue Scale (VAS) is a one-dimensional linear scale of 0 - 10 cm (0 cm representing no pain; 10 cm, severe pain) with values greater than 5 defined as moderate or severe. The Verbal Scale is a 4-point verbal score (on a categorical of: 0, none; 1, mild; 2, moderate; and 3, severe menstrual pain). Multidimensional scoring system defines the severity of dysmenorrhoea as mild, moderate and severe based on pain, limited activities and medication taken. The presence of other associated symptoms (including headache, dizziness, mood changes [nervousness], stomach cramps, nausea or vomiting, diarrhoea, constipation, oedema, and weakness) will be subjectively scored (no, mild, moderate, and severe) and recorded. Females with moderate or severe primary dysmenorrhoea will be invited to participate in the study.

Following consent, participants will be randomised to one of the following interventional trial arms:
1. Study drug: the extract of the roots of the South-African Uzara plant (Uzara® 40 mg coated tablets). This will be taken for five days (maximum), orally 2 tablets/8 hours for two doses then 1 tablet/8 hours. If there is mild or no pain 8 hours from the last dose, the use of drug should be stopped.
2. Control drug: ibuprofen 400 mg sugar coated tablets (Brufen®). This will be taken for five days (maximum) orally 1 tablet/6 hours. If there is mild or no pain 6 hours from the last dose, the use of drug should be stopped.

The interval between two successive menses will suffice as a wash-out period. The drug will be started at the onset of menstruation or when pain is felt to be impending, in the routine stated above. The participants will record the pain intensity they experienced right before taking intake of the medication (0 hour) and after 4, 12, 24, 48 - 60 and 96 - 120 hours.

For assessing the pain, both the VAS and Verbal Scale will be recorded at these 6 timepoints, as well as the multidimensional scoring system. The use of other analgesics is to be allowed for those receiving little or no relief of severe pain. This will be permitted 1 hour or more after the intake of the test drug and in such cases the last value of pain intensity/relief scores will be carried forward and used for the analysis. On using this rescue or backup medication, the type, dose, frequency of administration and the response will be recorded. The presence of other associated symptoms will be subjectively scored (no, mild, moderate, and severe) and recorded. Data entailing possible adverse events to the drug will be collected. Tolerability will be assessed by recording adverse reactions during drug intake. At the termination of the 2 cycle study period, the patients will be asked to rank the preparations in order of effectiveness.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Uzara®, ibuprofen

Primary outcome measure
1. Pain intensity difference at each point (PID-point) and the sum of pain intensity difference at the six designated points (SPID-6)
2. Difference in multidimensional scoring
3. The percentage of patients taking rescue medication
4. Time interval to rescue medication
5. Patient's global evaluation of study medication

Measured before taking intake of the medication (0 hour) and after 4, 12, 24, 48 - 60 and 96 - 120 hours.

Secondary outcome measures
Measures of safety:
1. Adverse events
2. Drug tolerability

Measured before taking intake of the medication (0 hour) and after 4, 12, 24, 48 - 60 and 96 - 120 hours.

Overall study start date
01/12/2010

Completion date
30/11/2011

Eligibility

Key inclusion criteria
1. Female students attending clinical classes in medicine (Faculty of Medicine) or nursing (High Institute of Nursery) at Ain Shams University Maternity Hospital and having moderate or severe spasmodic dysmenorrhoea (history of at least 6 consecutive months of moderate to severe dysmenorrhoea, with the pain starting one day before or on the day of onset of bleeding and lasting at least 1 day during menstruation) and requiring analgesic use for pain relief, in each of the last 3 consecutive cycles preceding admission into the study.
2. Aged 18 - 28 years of age at the time of the study
3. Regular cycles lasting 21 to 35 days with the actual menses periods lasting three to seven days
4. Signed written informed consent by the student to participate in the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Students who are/were married or planning to get married during the study period
2. Students on hormonal therapy during the last 6 months or those planning to take hormonal therapy including oral contraceptives during the study period
3. Known or suspected secondary dysmenorrhoea (major abdominal or pelvic surgery, endometriosis, pelvic inflammatory disease [PID], ovarian cysts, pathological vaginal secretion, chronic abdominal pain, inflammatory bowel disease, irritable bowel syndrome)
4. History of significant chronic constipation and/or recurrent colitis
5. Serious medical condition: having evidence of clinically relevant gynaecological, cardiovascular, haematologic, hepatic, gastrointestinal (especially active or severe peptic ulceration, or history thereof), renal, pulmonary (especially bronchial asthma or history thereof), endocrinologic, autoimmune diseases, neurologic or psychiatric disease, based on a clinical assessment and routine laboratory investigations
6. Regular intake of medications that are not allowed in the study (pain medications for any other reason including non-steroidal anti-inflammatory drugs [NSAIDs], digoxin, antidepressants, tranquilizers, hypnotics, sedatives, or sex hormones)
7. Any concomitant disease of condition that might require any intake of analgesic medication
8. Unwilling to comply with the protocol
9. Participation in another clinical trial in the last 3 months prior to the start of this study

Date of first enrolment
01/12/2010

Date of final enrolment
30/11/2011

Locations

Countries of recruitment
Egypt

Study participating centre
2 Mobarak St.
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Egypt
11341

Sponsor information

Organisation
Ain Shams University Maternity Hospital (Egypt)

Sponsor details
c/o Prof Karim H I Abd-El-Maeboud
Abbassia
Cairo
Egypt
11566

Sponsor type
Hospital/treatment centre

Website
http://med.shams.edu.eg/index.php

ROR
https://ror.org/00p59qs14

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Ain Shams University Maternity Hospital (Egypt)

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	13/08/2014		Yes	No