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Evaluation of the extended regimen versus standard regimen of oral contraceptive in premenstrual and/or menstrual symptoms

Submission date	Recruitment status	[X] Prospectively registered
26/08/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/10/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
15/04/2020	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
LB0901

Study information

Scientific Title
A randomised multicentre parallel-group, comparative, prospective, open label study to assess the effect of extended regimen versus standard regimen of the oral contraceptive 3 mg drospirenone/20 µg ethinyl estradiol in premenstrual and/or menstrual symptoms

Study objectives
This study aims to show the non-inferiority of the extended regimen compared to standard regimen of the oral contraceptive drospirenone/ethinyl estradiol in the treatment of premenstrual and/or menstrual symptoms.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Faculty of Medicine Jundiai approved on the 5th August 2010 (ref: 176 /10)

Study design
Randomised double-arm multicentre comparative prospective parallel groups open label trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Premenstrual symptoms

Interventions
Subjects will be randomised to receive either 3 mg drospirenone/20 µg ethinyl estradiol in extended regimen (168 days of uninterrupted treatment) or drospirenone 3 mg/ethinyl estradiol 20 µg in standard regimen (6 cycles of 24 days of treatment followed by 4-day tablet free interval).

Subjects will record the scores of symptoms and patterns of bleeding in a daily diary. Questionnaire for Quality of Life (Short WHOQOL) will be applied in visits C1 (after 1 month of treatment), C2 (after 3 months of treatment) and C4 (after 6 months of treatment).

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Drospirenone, ethinyl estradiol

Primary outcome measure
Percentage of reduction in the total score of symptoms as recorded in the Daily Symptom Report (DSR-17) after treatment with 3 mg drospirenone/20 µg ethinyl estradiol in extended regime compared to standard regime.

Secondary outcome measures
1. Bleeding pattern
2. Questionnaire for Quality of Life (Short WHOQOL) - Portuguese version, applied in visits C1, C3 and C4
3. Significant change in laboratory tests and clinical parameters

Overall study start date
10/01/2011

Completion date
28/02/2012

Eligibility

Key inclusion criteria
1. Females of child bearing age (18 - 39 years)
2. At least three regular menstrual cycles lasting between 25 and 35 days, with 3 - 7 days of bleeding, without occurrence of intermenstrual bleeding and without amenorrhoea
3. Willingness to contraception and to meet the requirements of the study
4. Available to receive telephone calls
5. Competence to consent to participate in the study and sign the ICF
6. Education of at least four years or good ability to understand spoken and written information as testified by investigator
7. Complaint of at least one physical symptom and one emotional symptom in the premenstrual and/or menstrual period with intensity greater than or equal to two points according to scores of "Daily Symptom Report (DSR-17)" recorded by patient in the screening phase

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
368 subjects randomised

Total final enrolment
348

Key exclusion criteria
1. Users of hormonal contraceptives less than three months before the study. Exception will be considered to users of combined oral contraceptives without drospirenone in formulation, used in conventional 21/7 regimen.
2. Use of depot medroxyprogesterone acetate less than six months before the study
3. History of severe depression, bipolar disorder, psychosis, history of drug or alcohol abuse in the past two years
4. Treatment with antidepressants or anxiolytics
5. Any condition in category 2, 3 or 4 of the Medical Eligibility Criteria of the World Health Organization for contraceptive use, except for smoking**
6. Women smoking more than 15 cigarettes/day or smokers aged over 35 years
7. Use of drugs that interfere with the effectiveness of combined oral contraceptives
8. Suspected or confirmed pregnancy
9. Clinically significant changes in laboratory parameters requested in the screening visit
10. Participation in another trial less than three months before the study
11. Relationship to staff members of the study

Date of first enrolment
10/01/2011

Date of final enrolment
28/02/2012

Locations

Countries of recruitment
Brazil

Study participating centre
250 Josef Kryss
São Paulo
Brazil
01140-050

Sponsor information

Organisation
LIBBS Farmaceutica Ltd (Brazil)

Sponsor details
250 Josef Kryss
São Paulo
Brazil
01140-050

Sponsor type
Industry

Website
http://www.libbs.com.br

ROR
https://ror.org/055kp8612

Funder(s)

Funder type
Industry

Funder Name
LIBBS Farmaceutica Ltd (Brazil)

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	30/03/2020	15/04/2020	Yes	No