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Effect of a food supplement on sexual function in women with low sexual desire

Submission date
18/03/2019

Recruitment status
No longer recruiting

Registration date
28/03/2019

Overall study status
Completed

Last Edited
02/05/2019

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Background and study aims
Women with low sexual desire may have problems when starting or having stable sexual relationships, and they may feel unsatisfied and experience marital disorders. Studies have demonstrated that women with low desire, low excitement, or sexual pain are clearly associated with negative feelings regarding their physical and emotional satisfaction, as well as their happiness. In addition, women suffering from those problems tend to experience much more negative emotions and psychological states than women with normal sexual activity.
Our objective was to study the effect of an extract with natural components on women with low sexual desire.
In this study, the multi-ingredient food supplement, Libicare®, has shown an improvement in desire, arousal, lubrication, orgasm, and sexual satisfaction domains, with a clear increase in free testosterone numbers and a decrease in SHBG levels in postmenopausal women.

Who can participate?
Postmenopausal women aged ≥ 45 and ≤ 65 (no natural menses for at least 1 year), with a stable partner and at risk of sexual dysfunction according to score of validated questionnaire.

What does the study involve?
All women were included at routine clinical visits and were treated with 2 tablets of Libicare®, one every 12 hours, daily for 2 months (9 weeks). Libicare® is an oral food supplement containing dry extracts of Trigonella foenum graecum, Turnera diffusa, Tribulus terrestris, and Ginkgo biloba.

What are the possible benefits and risks of participating?
All the participants have been informed, before their inclusion, of the possible risks and benefits, and of all the aspects of the study and have signed an Informed Consent expressing their willingness to participate.
Possible benefits: improving in sexual function.
Possible risks: due to characteristics of Libicare ingredients important risks were not expected.

Where is the study run from?
Instituto Palacios de Salud y Medicina de la Mujer, Madrid, Spain

When is the study starting and how long is it expected to run for?
August 2017 to November 2018

Who is funding the study?
Procare Health SL

Who is the main contact?
Dr Danial Khorsandi, danialkhorsandi92@gmail.com

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
LBC-0001

Study information

Scientific Title
Effect of a multi-ingredient based food supplement on sexual function in women with low sexual desire. Pilot study.

Study objectives
The Libicare® food supplement will improve sexual function in women.

Ethics approval required
Old ethics approval format

Ethics approval(s)

No approval needed.
The pilot study that has been presented has been carried out following a well-defined protocol, and in accordance with the main premises of Good Clinical Practices and the Declaration of Helsinki.

Primary study design
Observational

Study design
Observational prospective non-controlled pilot study

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Female sexual dysfunction.

Interventions
All women were included at routine clinical visits and were treated with 2 tablets of Libicare®, one every 12 hours, daily for 2 months (9 weeks). Libicare® is an oral food supplement containing dry extracts of Trigonella foenum graecum, Turnera diffusa, Tribulus terrestris, and Ginkgo biloba. Libicare® is manufactured by Procare Health (Barcelona, Spain).

All participants were visited at baseline (initial visit) and after 9 weeks (final visit).
Primary variable: Total score of Female Sexual Function Index (FSFI) at 9 weeks vs baseline.
Secondary variables: FSFI score for each domain, and levels of free testosterone and sex hormone binding globulin at 9 weeks vs baseline.
Serum levels of free testosterone and sex hormone-binding globulin (SHBG) were measured in the LABCO Laboratory. SHBG was measured with chemiluminescent immunoassay Immulite 2000 XPi (Siemens Healthcare Diagnostics, Eschborn, Germany). The estimation of serum free testosterone hormone levels was carried out using the ELISA technique (The DiaMetra Italy kit (DKO-015))

Intervention Type
Supplement

Primary outcome(s)
Sexual function measured using Female Sexual Function Index (FSFI) at 9 weeks vs baseline.

Key secondary outcome(s)
1. FSFI score for each domain at 9 weeks vs baseline.
2. Levels of free testosterone and sex hormone binding globulin at 9 weeks vs baseline.

Completion date
31/08/2019

Eligibility

Key inclusion criteria

1. Healthy, postmenopausal women (no natural menses for at least 1 year) aged ≥ 45 and ≤ 65. Hysterectomized patients should have an FSH level above 40 IU.
2. Stable partner, living together for at least 15 days a month and being sexually available.
3. Risk of sexual dysfunction established at FSFI score< 25.83.
4. Integrity of the vaginal mucosa (without lesions or bleeding).
5. Women willing to and capable of understanding and signing an informed consent after receiving an explanation on the nature of the whole study.
6. Consenting to participate in the study and signing the Informed Consent form.
7. No desire for pregnancy in the next 3 months.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
29

Key exclusion criteria
1. Pregnant women or with suspected pregnancy.
2. Within 3 months following delivery or abortion.
3. Breastfeeding women.
4. Women with severe pain in sexual relationships (DMS-V).
5. Non-diagnosed abnormal genital bleeding or presence of vaginal lesions.
6. Women with symptoms of vaginal infection or signs of any other genital infection.
7. Women allergic or hypersensitive to the components of the study treatment.
8. Severe psychiatric disorder.
9. Use of any hormonal treatment with estrogens, progestogens, or estrogens and progestogens within 3 previous months prior to selection.
10. Use of any other drug or experimental device within 30 days prior to selection.
• Any condition preventing the patient from participating in the study, at the researcher’s discretion.

Date of first enrolment
01/07/2017

Date of final enrolment
30/01/2018

Locations

Countries of recruitment
Spain

Study participating centre
Instituto Palacios de Salud y Medicina de la Mujer
Calle de Antonio Acuña, 9
Madrid
Spain
28009

Sponsor information

Organisation
Instituto Palacios de Salud y Medicina de la Mujer

ROR
https://ror.org/01kvepn75

Funder(s)

Funder type
Industry

Funder Name
Procare Health SL

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	30/04/2019	02/05/2019	Yes	No