

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

Submission date 18/03/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/03/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 02/05/2019	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> 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?
Procure Health SL

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

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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.

Study design

Observational prospective non-controlled pilot study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use contact details to request a participants information sheet.

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 measure

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

Secondary outcome measures

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.

Overall study start date

01/05/2017

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

Age group

Adult

Sex

Female

Target number of participants

This is a pilot study in which 29 patients were included

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

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<https://institutopalacios.com/>

ROR

<https://ror.org/01kvepn75>

Funder(s)

Funder type

Industry

Funder Name

Procare Health SL

Results and Publications

Publication and dissemination plan

We are going to publish a research paper in BMC woman's Health on July 2019

Intention to publish date

01/07/2019

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