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Subjective effects of a proprietary Eurycoma longifolia and Polygonum minus combination on well-being and sexual performance in patients with mild erectile dysfunction

Submission date
14/11/2011

Recruitment status
No longer recruiting

Registration date
23/02/2012

Overall study status
Completed

Last Edited
08/12/2015

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The root of the flowering plant Eurycoma longifolia (Tongkat Ali) has been used as a traditional medicine and promoted as a tonic, energy enhancer, and aphrodisiac. In this study, a commercial product containing an extract of Eurycoma longifolia, 'Physta', was tested for its effectiveness and safety for improving sexual performance and well-being in men with reduced sexual potency. The product also contained an extract of Polygonum minus, added for its antioxidant benefits.

Who can participate?
Men aged 40-65 with mild erectile dysfunction.

What does the study involve?
Participants are randomly allocated to receive either a combination of extracts of Eurycoma longifolia and Polygonum minus, or an identical placebo (dummy), daily for 12 weeks. Participants complete erectile dysfunction and quality of life questionnaires at the start of the study and after 6 and 12 weeks.

What are the possible benefits and risks of participating?
Benefits include improved sexual performance, quality of life and well-being.

Where is the study run from?
Staywell Research clinical research site in Northridge, CA, USA.

When is the study starting and how long is it expected to run for?
September 2009 to August 2010.

Who is funding the study?
Biotropics Malaysia.

Who is the main contact?
Jay Udani

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
BIOT1000

Study information

Scientific Title
Subjective effects of a proprietary Eurycoma longifolia and Polygonum minus combination on well-being and sexual performance in patients with mild erectile dysfunction: a randomized controlled trial

Study objectives
The purpose of this study is to compare the effects of a proprietary Tongkat ali/Polygonum minus combination with placebo on well-being and sexual performance in patients with mild erectile dysfunction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Copernicus Group Institutional Review Board, 14/09/2009

Study design
Randomized double-blind placebo-controlled parallel-design trial

Primary study design
Interventional

Secondary study design
Randomised controlled 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
Erectile dysfunction

Interventions
Males aged 40-65 with mild erectile dysfunction were studied as outpatients in this double-blind, randomized, placebo-controlled, parallel-group pilot trial. Participants, researchers, and individuals dealing with the data were blinded to the treatment group.

Subjects received one of the following two interventions: identical placebo or 300mg of a combination of proprietary freeze-dried water extracts of Eurycoma longifolia + Polygonum minus daily for twelve weeks.

Thirty men were randomized to the study (N=15 per group), and 26 completed the study (N=12 in the treatment group). These 26 subjects were included in the analysis.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Eurycoma longifolia + Polygonum minus

Primary outcome measure
1. Index of Erectile Function (IIEF-5) is a six-point scale ranging from 0 to 5. The higher the score, the better the function
2. Erectile Dysfunction Inventory for Treatment Satisfaction (EDITS) Questionnaire is a point scale ranging from 0 to 4
3. Percentage of successful sexual intercourse attempts (SIA) (from patient event logs) 10 questions most of which are yes or no and are coded as 1 or 0, respectively
4. Erection Hardness Scale (EHS) is a four-point scale, with scores ranging from 1 to 4
5. Sexual Health Inventory Questionnaire is a six-point scale for each question, ranging from 0 to

5
6. Aging Male Symptom Score is a six-point Likert scale ranging from 0 to 5. A higher score indicates worse function

Measured at screening, baseline, week 6, and week 12

Secondary outcome measures
1. Self-Esteem and Relationship Questionnaire (SEAR) uses a six-point Likert scale ranging from 0 to 5. A higher score indicates better function
2. Beck Depression Index and Beck Anxiety Index The Beck Depression Inventory and Beck Anxiety Inventory score individual items on a four-point scale (0-3). Scores across domains are summed. Total scores ≥21 indicate concern for depression.

Measured at screening, baseline, week 6, and week 12

Overall study start date
22/09/2009

Completion date
11/08/2010

Eligibility

Key inclusion criteria
1. Male subjects between the ages of 40 and 65 at the time of screening, and in a stable heterosexual relationship for at least six months. Both partners had to agree to attempt intercourse at least once a week on average during the study.
2. Subjects with testosterone levels ≤ 450ng/dL
3. Index of erectile dysfunction scores between17-25

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
26

Key exclusion criteria
1. Subjects with a history of prostate cancer, elevated prostate-specific antigen (PSA), benign prostate hypertrophy (BPH) scores ≥ 40, penile anatomical abnormalities, premature ejaculation
2. Cardiovascular disease, resting hypotension (resting systolic blood pressure <90mmHg) or hypertension (resting systolic blood pressure >170mmHg or diastolic pressure >110mmHg)
3. Primary hypoactive sexual desire
4. Seizures
5. Hereditary degenerative retinal disorders or loss of vision

6. Liver disease
7. Clinically significant chronic hematological disease, bleeding disorders
8. Significant active peptic ulceration
9. Symptomatic postural hypotension or syncope within the previous six months
10. Malignancy within the previous five years (other than squamous or basal cell)
11. A positive test for hepatitis B surface antigen or hepatitis C
12. Alcoholism (an alcohol screening score ≥2)
13. Congenital spinal cord deformities or traumatic injuries, congenital or traumatic brain injuries
13. An abnormal prostate exam during the screening visit

Date of first enrolment
22/09/2009

Date of final enrolment
11/08/2010

Locations

Countries of recruitment
United States of America

Study participating centre
18250 Roscoe Boulevard Suite 220
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Sponsor information

Organisation
Biotropics Malaysia Berhad (Malaysia)

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Sponsor type
Industry

ROR
https://ror.org/00jsvb253

Funder(s)

Funder type
Industry

Funder Name
Biotropics Malaysia (Malaysia)

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