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Efficacy and safety of Cappra in erectile dysfunction patients

Submission date
20/05/2012

Recruitment status
No longer recruiting

Registration date
28/05/2012

Overall study status
Completed

Last Edited
26/09/2014

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Several medications for the treatment of erectile dysfunction are on the market nowadays. However, those medications may have a strong reaction or side effects in patients with certain conditions such as heart or coronary diseases. Herbal substances may be an alternative. Cappra is registered in Thailand as a herbal medication. Its ingredients have been proven to be safe and have been used in Chinese medication for decades. The aim of this study is to find out whether Cappra is effective and safe for the treatment of erectile dysfunction.

Who can participate?
Men aged 35 and above with erectile dysfunction.

What does the study involve?
Patients were randomly allocated into two groups. The patients in the first group received three tablets of Cappra during the first 2-weeks period and three placebo (dummy) tablets during the second 2-week period, with a 7-day break in between the first and second periods. The other group received both Cappra and placebo but in the opposite order to the first group. All patients were instructed to take one tablet of either Cappra or placebo 1 hour before sexual intercourse and they had to take three tablets within 2-week period.

What are the possible benefits and risks of participating?
Patients may benefit from improved sexual ability but may have some risks of side effects such as dizziness, fatigue or muscle cramp.

Where is the study run from?
This study was mainly performed at Faculty of Pharmaceutical Sciences, Chulalongkorn University in Bangkok, Thailand.

When is the study starting and how long is it expected to run for?
The study ran from June 2011 to April 2012.

Who is funding the study?
This study was funded by CAPP Innovation Research and Development Center (CIRD) (Thailand).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
03/55

Study information

Scientific Title
Efficacy and safety of Cappra in mild to moderate erectile dysfunction patients

Study objectives
Cappra (a Chinese herbal medicine) is efficient and safe for the treatment of mild and mild to moderate erectile dysfunction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Joint Research Ethics Committee in Bangkok, Thailand, 02/01/2011, ref: JREC 013/53

Study design
Randomized double-blind placebo-controlled two-period cross-over design

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
Mild and mild to moderate erectile dysfunction patients

Interventions
Patients received information regarding the study protocol, its rationale and the potential risks (in Thai language) as well as six tablets, divided into two packages: three tablets of Cappra and three tablets of placebo, for use during the study period.

The patients were randomized into two groups using a computer-generated random sampling table in which the identity of those in each group was concealed from both the investigators and patients. The patients in the first group received three tablets of Cappra during the first period (2 weeks) and three tablets of placebo during the second period; a wash-out period of 7 days was necessary between the first and second period. The other group received both Cappra and placebo at the same manner as the first group but in the opposite order to the first group. All patients were instructed to take one tablet of either Cappra or placebo 1 hour before sexual intercourse and they had to take three tablets within the 2-week period.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The difference of the score from International Index of Erectile Function-5 (IIEF-5) self-questionnaire before and after taking the medications. They must fill the same questionnaire three times, which are at the time of enrollment to this study, at the end of the first period and at the end of the second period.

Secondary outcome measures
Adverse reaction or side effects experienced after taking Cappra. All adverse reactions will be analyzed by Nanranjo's algorithm to identify whether Cappra was the cause of those adverse reactions.

Overall study start date

01/06/2011

Completion date
30/04/2012

Eligibility

Key inclusion criteria
1. Men aged 35 and above with mild and mild to moderate erectile dysfunction analyzed according to the International Index of Erectile Function-5 (IIEF-5)
2. All subjects must be sexually active and have sexual intercourse at least three times within 2 weeks

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
70 patients

Key exclusion criteria
1. Patients with uncontrolled hypertension or uncontrolled diabetes mellitus within 3 months before enrollment into the study
2. Patients with liver or kidney dysfunction
3. Patients with active upper gastrointestinal bleeding
4. Patients who use any medications which may affect sexual function such as testosterone, phosphodiesterase type 5 inhibitor or any herbal substances claimed for improving sexual function
5. Patients who take medications which may have an interaction with Cappra, such as warfarin, antiplatelet agents, potassium sparing diuretics, monoamine oxidase inhibitors, and selective serotonin reuptake inhibitors
6. Patients who allergic to sulfonamide
7. Patients who allergic to honey or bee pollen
8. Patients with speech or reading problems
9. Participants also left the project when they could not comply with the study protocol, were unwilling to continue with the study or when the physician opined that patients may be harmed by the study protocol

Date of first enrolment
01/06/2011

Date of final enrolment
30/04/2012

Locations

Countries of recruitment
Thailand

Study participating centre
Department of Pharmacy Practice
Bangkok
Thailand
10330

Sponsor information

Organisation
CAPP Innovation Research and Development Center (CIRD) (Thailand)

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Sponsor type
Research organisation

Funder(s)

Funder type
Research organisation

Funder Name
CAPP Innovation Research and Development Center (CIRD) (Thailand), ref: CIRD 11/54

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