

Efficacy and safety of Cappa in erectile dysfunction patients

Submission date 20/05/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/05/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 26/09/2014	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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. Cappa 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 Cappa 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 Cappa 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 Cappa and placebo but in the opposite order to the first group. All patients were instructed to take one tablet of either Cappa 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?
Associate Professor Pornanong Aramwit
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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 Cappedra 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 Cappedra 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 Cappedra 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 Cappedra 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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

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 Cappa, 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)

Funder(s)

Funder type

Research organisation

Funder Name

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration