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Honey Cocktail Study

Submission date
14/06/2016

Recruitment status
No longer recruiting

Registration date
16/06/2016

Overall study status
Completed

Last Edited
29/01/2019

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Menopause is an important stage in a woman's life, in which they stop having periods and are no longer able to get pregnant naturally. Following the menopause, women have a higher risk of developing long-term health conditions such as osteoporosis (weak bones), cardiovascular disease (disease of the heart and blood vessels), and dementia, as the hormone changes following menopause cause changes in the body. Nutritional supplements can help older women to stay healthy and energetic, as they provide important nutrients that the body is lacking. Honey and other hive products such as royal jelly, propolis, bee pollen, bee bread and bee could have been reported to contain substances that are nutritious and have been used to treat a range of conditions. So far, studies looking at the effects of honey in menopausal women are limited. Animal studies have shown that Tualang honey (a Malaysian jungle honey) can help to regulate hormones and improve health of the female reproductive system in mice, as well as restoring bone density in rats. Other products such as bee bread and royal jelly contain higher mineral, free fatty acids, protein and essential amino acids compared to honey. Therefore, the combination of bee hive product called Honey Cocktail is expected to be more effective than honey alone. The aim of this study is to investigate the health benefits of Tualang honey compared to Honey Cocktail in menopausal women.

Who can participate?
Healthy women aged 45 to 65 years old who have been menopausal for more than five years.

What does the study involve?
Participants are randomly allocated to one of two groups. At the start of the study, all participants attend a study visit at which they complete a questionnaire, have scans to measure their pelvic health and bone density, and have blood samples taken. Those in the first group are then asked to consume one 20g sachet of Tualang honey every morning for 12 months. Those in the second group are asked to consume one 20g sachet of Honey Cocktail every morning for 12 months. During the 12 months of the study, participants are asked to come to the study centre every three months for a check-up and to be interviewed about any side effects they have experienced. After 12 months, participants repeat the initial measures taken before treatment began in order to find out if there have been any changes to their cardiovascular (heart and blood vessels) health, hormone levels, bone density and psychosexual health (mental and emotional attitudes to sex).

What are the possible benefits and risks of participating?
Participants benefit from having expenses relating to their participation paid during the study. There are no notable risks involved with participating.

Where is the study run from?
Hospital Universiti Sains Malaysia (Malaysia)

When is the study starting and how long is it expected to run for?
September 2011 August 2016

Who is funding the study?
Universiti Sains Malaysia (Malaysia)

Who is the main contact?
Mrs Siti Zubaidah Ab Wahab

Contact information

Type(s)
Scientific

Contact name
Mrs Siti Zubaidah Ab Wahab

Contact details
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16150

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1001/PPSP/812098

Study information

Scientific Title
A comparative study on the effects of tualang honey versus honey cocktail on physiological, psychosexual changes and safety among postmenopausal women

Study objectives
1. There is significant improvement of cardiovascular parameters in Honey Cocktail group compared to Tualang honey group
2. There is significant improvement of hormonal profiles in Honey Cocktail group compared to Tualang honey group
3. There is significant improvement of bone densitometry and Honey Cocktail group compared to Tualang honey group
4. There is significant improvement of oxidative stress status in Honey Cocktail group compared to Tualang honey group
5. There is significant improvements in psychosexual changes in Honey Cocktail group compared to Tualang honey group
6. There is no significant difference in safety profile between Honey Cocktail group and Tualang honey group

Ethics approval required
Old ethics approval format

Ethics approval(s)
Jawatankuasa Etika Penyelidikan Manusia USM (JEPeM), 08/11/2011, ref: USMKK/PPP/JEPeM [243.3.(3)]

Study design
Single-centre prospective double-blind randomised parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Menopause

Interventions
Participants are randomised based on the randomization blocks of four and will be assigned to either receive Tualang honey or Honey Cocktail base on a randomization table which was computer generated. Participants will only identified based on their identification number and will be allocated to the study treatment as they are recruited.

Tualang honey group: Participants will receive one 20g sachet of Tualang honey every morning for 12 months.

Honey Cocktail group: Participants will receive one 20g sachet of Honey Cocktail every morning for 12 months.

The study participants are advised to come at 3 monthly intervals at CTU for the next 12 months at which they are interviewed about compliance and side effects experienced and examined by the clinicians involved in the trial. At 12 months, participants attend a follow up appointment at which questionnaires are undertaken, blood samples are taken, bone density is measured, and a pelvic ultrasound is completed.

Intervention Type
Supplement

Primary outcome measure
1. Blood pressure is measured by an automatic blood pressure monitor at baseline and 12 months
2. Fasting lipid profile is measured by analysing blood samples using an automated lipid analyser at baseline and 12 months
3. Follicle stimulating hormone, luteinizing hormone, testosterone levels and estradiol levels are measured by analysing blood samples using an automated hormone analyser at baseline and 12 months
4. Bone density is measured using a mini bone ultrasound device at baseline and 12 months
5. Oxidative stress is measured by analysing blood samples at baseline and 12 months

Secondary outcome measures
1. Psychosexual changes are measured using the Validated Malay version of Women's Health Questionnaire and the Validated Malay version of Female Sexual Function Index at baseline and 12 months
2. Adverse events are measured through interviews and examinations by the clinician in charge of the trial and the completiong of an Adverse Events Form at 6 months and 12 months
3. Serious adverse event rate is measured by calculating the incidence of death, in-patient hospitalization, malignancy, and/or result of an overdose within 6 months and 12 months
4. Pelvic pathology is assessed using pelvic ultrasound at baseline and 12 months
5. Liver and renal function is measured using kidney and liver function tests on blood samples at baseline and 12 months

Overall study start date
01/09/2011

Completion date
31/08/2016

Eligibility

Key inclusion criteria
1. Aged 45 -65 years old
2. Surgically or naturally menopausal for more than five years
3. Healthy (as determined by laboratory results, medical history and physical exam) with only stable medical problems
4. Provision of written informed consent to participate

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Female

Target number of participants
50 subjects per group

Key exclusion criteria
1. Abnormal pelvic ultrasound examination
2. Major uncontrolled psychiatric disorders
3. History of alcohol or drug abuse
4. Any renal or hepatic disorders
5. Active peptic ulcer or bleeding disorder
6. Unstable cardiac history, defined as: myocardial infarction (MI); coronary angioplasty or bypass graft(s); valvular disease or repair; unstable angina pectoris; transient ischemic attack (TIA); cerebrovascular accidents (CVA); congestive heart failure; or coronary artery disease (CAD) within the past 12 months
7. Allergy or sensitivity to study supplement ingredients
8. Not on HRT within 3 month prior to randomization
9. Use of oral natural herbal health products/dietary supplements within 3 month prior to randomization
10. Taking medication for the treatment of bone, including: Rocatriol, Fosamax and Protaxos within 3 months prior to randomization
11. Clinically significant abnormal laboratory results at screening
12. Participation in a clinical research trial within 30 days prior to randomization
13. Any other condition which in the Investigator's opinion may adversely affect the subject's ability to complete the study or its measures or which may pose significant risk to the participant

Date of first enrolment
16/06/2012

Date of final enrolment
15/06/2015

Locations

Countries of recruitment
Malaysia

Study participating centre
Hospital Universiti Sains Malaysia
Clinical Trial Unit
Jalan Raja Perempuan Zainab 2
Kubang Kerian

Kelantan
Malaysia
16150

Sponsor information

Organisation
University of Science, Malaysia (Universiti Sains Malaysia)

Sponsor details
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Sponsor type
University/education

Website
http://www.research.usm.my/

ROR
https://ror.org/02rgb2k63

Funder(s)

Funder type
University/education

Funder Name
University of Science, Malaysia (Universiti Sains Malaysia)

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2018	29/01/2019	Yes	No