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Effects of Tualang honey on quality of life and biochemical markers in breast cancer patients treated with anastrozole

Submission date	Recruitment status	[_] Prospectively registered
28/08/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/09/2016	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
09/09/2016	Cancer	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Breast cancer is the most common type of cancer among women. Honey has been reported to have various health properties, including antimicrobial, antioxidant and anti-inflammatory properties. Honey is traditionally used among Malaysian breast cancer patients in the belief that it will improve their health. However, to the knowledge of the researchers running this study, no study has been reported on how safe it is and how well it works among breast cancer patients. Therefore, the aim of this study is to determine the safety profile (i.e. chemistry, pharmacology, therapeutic effects and side effects) of Malaysian Tualang honey supplementation on both quality of life and so-called biochemical markers in breast cancer patients treated with anastrozole (a drug for treating advanced breast cancer in post-menopausal women).

Who can participate?
Postmenopausal women with advanced breast cancer and being treated with anastrozole.

What does the study involve?
Initially, all participants visit the study centre after fasting (not eating) for at least 10 hours. A blood sample is taken from each participant for analysis. Participants are then randomly allocated into one of two groups. Those in group 1 are given honey (in a sachet) to take every day for 12 weeks. Those in group 2 are not given honey to take. All patients are advised to report any adverse (side) events to the researcher during this time period. Sachets are counted to check that participants in group 1 are taking the honey. After 3 months, all participants are asked to go back to the study centre to give another blood sample for assessment. Participants are informed about study completion and advised to continue normal routine follow-up.

What are the possible benefits and risks of participating?
There are no risks associated with taking part in this study

Where is the study run from?
Nuclear Medicine, Oncology and Radiotherapy Clinic, University of Science Malaysia Hospital

When is the study starting and how long is it expected to run for?
January 2013 to August 2016

Who is funding the study?
University of Science Malaysia

Who is the main contact?
Dr Mahaneem Mohamed
mahaneem@usm.my

Contact information

Type(s)
Scientific

Contact name
Dr Mahaneem Mohamed

ORCID ID
http://orcid.org/0000-0001-9333-1957

Contact details
Department of Physiology
School of Medical Sciences
University of Science Malaysia
Kubang Kerian
Malaysia
16150
+6097676158
mahaneem@usm.my

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
USMKK/PPP/JEPeM[260.3(21)]

Study information

Scientific Title
Effects of Tualang honey on quality of life and biochemical markers in breast cancer patients treated with anastrozole: an open-label randomized controlled trial study

Study objectives

Honey supplement is safe, and significantly improves quality of life and biochemical markers in postmenopausal breast cancer patients treated with anastrozole

Ethics approval required
Old ethics approval format

Ethics approval(s)
Human Research Ethics Committee Universiti Sains Malaysia, ref: USMKK/PPP/JEPeM[260.3.(21)]

Study design
Open-label randomized controlled trial study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Breast cancer in postmenopausal women

Interventions
Eighty-four postmenopausal breast cancer patients from Oncology Clinic, Universiti Sains Malaysia Hospital with stages I, II, and III, and treated with anastrozole (1 mg/day) are randomly assigned into two groups (n=42/group): (1) control (without honey) and (2) honey (20 g/day of Tualang honey for 12 weeks) groups. Tualang honey is supplied by Federal Agricultural Marketing Authority, Malaysia. They are briefed regarding the study and written consent is obtained. They are informed to come again and fast for at least 10 hours for the next visit (visit 1). At visit 1 (Month 0, baseline), a blood sample of 15 ml is obtained for biochemical parameters assessment. For the honey group, oral honey supplement 20 g daily (in sachet) for 3 months is given. All patients are advised to report any adverse events to the researcher. The patient's compliance is monitored by sachet counting. During visit 2 (Month 3), blood sample of 15 ml is obtained for biochemical parameters assessment. Patients are informed about study completion and advised to continue normal routine follow-up.

Randomization is performed by computer-generated random allocations sequence by simple randomization which is obtained from http://www.randomization.com. All the eligible subjects are labelled with numbers according to the sequence of attending the clinic during visit 1. Tualang honey (20g/day orally) is provided according to the randomization list.

Intervention Type
Supplement

Primary outcome measure
1. Quality of life status by using Quality of Life Questionnaire-Core 36 (EQRTC-QLQ-C30)
2. Blood oxidative stress status by assessing the levels of malonaldehyde, total antioxidant status, protein carbonyl, reduced glutathione (GSH): oxidised glutathione (GSSG) ratio, erythrocyte superoxide dismutase, catalase, glutathione peroxidase using commercial kits
3. Blood breast cancer markers which include carcinoembryonic antigen and CA15-3 using commercial kits

All these outcomes are measured at baseline (Visit 1) and after 3 months (Visit 2)

Secondary outcome measures
1. Safety profile which include full blood count, fasting blood glucose, liver function test and renal function test
2. Blood inflammatory markers which include high-sensitive C-reactive protein (hsCRP), interleukin-6 (IL-6), interleukin 1β (IL-1β) and tumour necrosis factor- α (TNF- α) using commercial kits
3. Blood bone markers which include C-terminal telopeptide of type 1 collagen (CTX) and procollagen type 1 N propeptide (P1NP) using commercial kits
4. Blood estradiol using commercial kits

All these outcomes are measured at baseline (Visit 1) and after 3 months (Visit 2)

Overall study start date
05/01/2013

Completion date
02/08/2016

Eligibility

Key inclusion criteria
Postmenopausal women treated with anastrozole and with breast cancer stages I, II and III estrogen receptor (ER+) positive and/or progesterone receptor (PR+) positive.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Target total recruitment of participants is 84 (42 participants per group) with considering the presence of drop-outs.

Key exclusion criteria
Any subject that has history of allergy to honey, severe infection, and/or receiving hormone and /or replacement therapy are excluded from this study.

Date of first enrolment
23/09/2014

Date of final enrolment
02/08/2016

Locations

Countries of recruitment
Malaysia

Study participating centre
Nuclear Medicine, Oncology and Radiotherapy Clinic, University of Science Malaysia Hospital
Nuclear Medicine, Oncology and Radiotherapy Clinic
Universiti Sains Malaysia Hospital
Universiti Sains Malaysia
Kubang Kerian, Kelantan
Malaysia
16150

Sponsor information

Organisation
University of Science, Malaysia (Universiti Sains Malaysia)

Sponsor details
Division of Research & Innovation
Level 6, Chancellory
Gelugor, Penang
Malaysia
11800
+604 - 653 3108 / 3988 / 5019
rcmo@usm.my

Sponsor type
University/education

ROR
https://ror.org/02rgb2k63

Funder(s)

Funder type

University/education

Funder Name
University of Science Malaysia

Results and Publications

Publication and dissemination plan
Plan to publish in at least 3 international journals on safety profile, quality of life and biochemical markers in end of 2016 and in 2017.

Intention to publish date
31/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration