

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

Submission date 28/08/2016	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 18/09/2016	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 09/09/2016	Condition category Cancer	☐ Individual participant data ☐ 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
<https://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

Protocol serial number
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)

Primary study design

Interventional

Study design

Open-label randomized controlled trial study

Study type(s)

Treatment

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(s)

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)

Key secondary outcome(s)

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 1 β (IL-1 β) 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)

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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)

ROR

<https://ror.org/02rgb2k63>

Funder(s)

Funder type

University/education

Funder Name

University of Science Malaysia

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration