The Effects of Tualang Honey on Postmenopausal Women

This study has been completed.

First Received on February 22, 2011. No Changes Posted

Sponsor:	University of Science Malaysia
Information provided by:	University of Science Malaysia
ClinicalTrials.gov Identifier:	NCT01300676

Purpose

Despite evidence supporting the benefits of hormone replacement therapy (HRT), only 15% of postmenopausal women currently use HRT (1). The leading reasons why women refuse or discontinue HRT are fear of malignancy, side effects such as vaginal bleeding, weight gain, depressed mood, and breast tenderness, and social reasons such as regarding menopause as a natural transition, not as a disease that requires treatment. Millions of women expressed their concern on the safety of hormone replacement therapy since the data from the Women's Health Initiative (WHI) study was released, which reported an increased risk of cardiovascular disease, breast cancer, stroke and thromboembolic disease with conjugated equine estrogen plus medroxyprogesterone acetate compared with placebo (2). The study has also demonstrated that quality of life (3) and cognition (4) were no better in the HRT group than the placebo group. In view of these problems, women are increasingly turning to alternative therapies in an effort to manage their menopausal symptoms (1).

Menopause is associated with decreasing sex steroid levels. The effect of menopause on circulating androgen levels has been studied by several investigators with variable findings. The levels of testosterone and androstenedione appear to show a small but significant decrease just before or within the first 2 years after menopause, with a decrease in testosterone amounting to approximately 15% (5,6). Unlike the abrupt decrease in estradiol levels associated with menopause, circulating testosterone, DHEA, and DHEAS levels decrease more gradually, beginning in the years before menopause and continuing thereafter (6,7). As a consequence, some women may experience symptoms of androgen decrease in the period before cessation of menses. By giving Tualang Honey to these postmenopausal women, it is postulated that the symptoms of androgen deficiency or menopausal symptoms should be reduced.

The investigators have also reported that tualang honey given to ovariectomised rats, an animal model for postmenopausal states for two weeks significantly increased the free testosterone and progesterone plasma levels, but no significant effect was seen in the beta-estradiol level. There were significant increased in the thickness of vaginal epithelium and vaginal epithelial-muscular layers. Proliferation of the squamous epithelium with vacuolation of some of the squamous cells were noted in the honey treated animals implying that there were increased in mucopolysacharide content. Uterine weight, endometrial and circular muscle thickness were significantly increased in honey treated animal with cystic changes noted over the glands (8).

To date, there are no clinical studies looking at the effects of Tualang Honey on perimenopausal women. In view of the initial evidence that it is a phytoestrogen from animal studies and has androgenic properties as well, it should have a beneficial effect to these women in terms of improvement in their menopausal symptoms, changes in their endogenous hormonal profile and increase in bone mineral density.

Condition	Intervention	Phase
Postmenopausal Syndrome	Drug: Tualang honey	Phase 2 Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Single Blind (Outcomes Assessor)
Primary Purpose: Prevention

Official Title: The Effect of Tualang Honey and Hormonal Replacement Therapy (HRT) on Safety Profiles Among Postmenopausal Women

Resource links provided by NLM:

MedlinePlus related topics: Bone Density Menopause

Drug Information available for: Estradiol Estradiol cypionate Estradiol valerate Estradiol acetate

U.S. FDA Resources

Further study details as provided by University of Science Malaysia:

Primary Outcome Measures:

- changes in haematological function [Time Frame: 4 months]
  [Designated as safety issue: No]

  To evaluate the safety profile of honey in term of haematological and biochemical profile

- changes in liver function [Time Frame: 4 months] [Designated as safety issue: No]

  To evaluate the safety profile of honey in term of haematological and biochemical profile

- changes in renal function [Time Frame: 4 months] [Designated as safety issue: No]

  To evaluate the safety profile of honey in term of haematological and biochemical profile

Secondary Outcome Measures:

- changes in cardiovascular parameters [Time Frame: 4 months]
  [Designated as safety issue: No]

  To assess the changes in cardiovascular parameters
  - blood pressure
  - waist circumference
  - total cholesterol
  - high density lipoprotein
  - low density lipoprotein
  - fasting glucose

- changes in hormonal level [Time Frame: 4 months] [Designated as safety issue: No]
  - follicular stimulating hormone (FSH)
  - luteinizing hormone (LH)
  - testosterone
  - estradiol

- changes in bone density [Time Frame: 4 months] [Designated as safety issue: No]

To assess the effects on bone density through bone densitometry (DEXA)

Enrollment:	79
Study Start Date:	March 2009
Study Completion Date:	June 2010
Primary Completion Date:	January 2010 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Active Comparator: Tualang Honey Group 1: Subjects receiving 20 g/day of Tualang honey. The honey used was from a single batch honey supplied by Federal Agricultural Marketing Authorities (FAMA), Malaysia, evaporated by FAMA to achieve a water content of about 20%, submitted to Sterile Gamma company at Shah Alam, Selangor for sterilization at 25 kGy and packed in 20 g sachet in collaboration with School of Pharmaceutical Sciences laboratory.	Drug: Tualang honey This was a randomized, prospective, clinical study to evaluate the effect of Tualang honey in comparison with HRT. Subjects will be confined to healthy postmenopausal women who were naturally menopause for more than one year. The study period was four months. A total of 79 patients were recruited. Group 1: Subjects receiving 20 g/day of Tualang honey. The honey used was from a single batch honey supplied by Federal Agricultural Marketing Authorities (FAMA), Malaysia, evaporated by FAMA to achieve a water content of about 20%, submitted to Sterile Gamma company at Shah Alam, Selangor for sterilization at 25 kGy and packed in 20 g sachet in collaboration with School of Pharmaceutical Sciences laboratory. Group 2: Subjects receiving hormonal replacement therapy (Femoston®), also known as Femo conti 1/5 (contain 1 mg Estradiol valerate and 5 mg Dydrogesterone) supplied by Solvay Pharma Malaysia. Other Name: Femo conti 1/5 (contain 1 mg Estradiol valerate and 5 mg Dydrogesterone)
No Intervention: Group 2 Group 2: Subjects receiving hormonal replacement therapy (Femoston®), also known as Femo conti 1/5 (contain 1 mg Estradiol valerate and 5 mg Dydrogesterone) supplied by Solvay Pharma Malaysia.	Drug: Tualang honey This was a randomized, prospective, clinical study to evaluate the effect of Tualang honey in comparison with HRT. Subjects will be confined to healthy postmenopausal women who were naturally menopause for more than one year. The study period was four months. A total of 79 patients were recruited. Group 1: Subjects receiving 20 g/day of Tualang honey. The honey used was from a single batch honey supplied by Federal Agricultural Marketing Authorities (FAMA),

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Show Detailed Description

Eligibility

Ages Eligible for Study: 45 Years to 65 Years
Genders Eligible for Study: Female
Accepts Healthy Volunteers: Yes

Criteria

Inclusion Criteria:

- Age more than 45 and less than 65 years old
- No present active medical, surgical and gynaecological problems
- Body mass index 18-35 kg / m2
- Not on hormone replacement therapy for more than 3 months
- Subject who has given written informed consent to participate in the study and understand the nature of the study
- Not illiterate

Exclusion Criteria:

- Taking any form of herbal extract in the last 3 months before study entry.
- History of drug or alcohol abuse.
- Following ovariectomy.
- History of breast or cervical carcinoma.
- Taking medication that affect bone metabolism, including glucocorticoid, anticonvulsant and methotrexate.
- Clinical relevant cardiovascular, gastrointestinal, hepatic, neurologic, endocrine, haematologic or other major systemic diseases making implementation of the protocol or other interpretation of the study result difficult.
- Mental condition rendering the subject unable to understand the nature, scope and possible consequences of the study.
- Evidence of uncooperative attitude, including poor compliance
- Inability to attend follow-up visit.
- Subject with any other medical condition (for example uncontrolled infection) that may, in the opinion of the Investigator, interfere with the study objective.
- Endometrial thickness more than 0.5 cm detected from pelvic ultrasonography.

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT01300676

Locations

Malaysia

Clinical Trial Unit, Hospital USM
Kubang Kerian, Kelantan, Malaysia, 16150

Sponsors and Collaborators

University of Science Malaysia

More Information

No publications provided

Responsible Party:	Associate Professor Dr Nik Hazlina Nik Hussain, USM
ClinicalTrials.gov Identifier:	NCT01300676 History of Changes
Other Study ID Numbers:	(USMKK/PPP/JEPeM (198.3(11)), (USMKK/PPP/JEPeM (198.3(11))
Study First Received:	February 22, 2011
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Health Authority:	Malaysia: Ministry of Health

Keywords provided by University of Science Malaysia:

- Tualang honey
- HRT
- safety profiles
- cardiovascular parameters
- hormonal levels
- bone changes
- postmenopausal women

Additional relevant MeSH terms:

- Dydrogesterone
- Estradiol
- Polyestradiol phosphate
- Estradiol valerate
- Estradiol 3-benzoate
- Estradiol 17 beta-cypionate
- Progestins
- Hormones
- Hormones, Hormone Substitutes, and Hormone Antagonists
- Physiological Effects of Drugs
- Pharmacologic Actions
- Estrogens
- Contraceptive Agents
- Reproductive Control Agents
- Therapeutic Uses
- Contraceptive Agents, Female

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