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An open label pilot study to evaluate the effectiveness of a proprietary krill oil formulation in the relief of troublesome symptoms of the menopause

Submission date
27/04/2016

Recruitment status
No longer recruiting

Registration date
23/06/2016

Overall study status
Completed

Last Edited
15/10/2020

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
Around 80% of women experience some symptoms during the menopause, typically lasting about 4 years after the last period, but continuing for up to 12 years in about 10% of women. Those symptoms include vasomotor symptoms (hot flushes and night sweats), vulvovaginal atrophy/dyspareunia, sleep disturbance, adverse mood, a lack of interest in sex, headaches, joint and muscle stiffness, memory and concentration loss, and consequently quality of life may be severely affected. Treatments used to relieve menopause-related symptoms include lifestyle advice, hormone replacement therapy (HRT), antidepressants, herbal remedies, and other complimentary/alternative therapies. Given the issues with the potential safety and side effects of many prescribed medications, the lack of effectiveness of a number of lifestyle interventions, and the clear desire from many women to initially use more natural approaches, there is a need for an effective nutritional solution for managing menopausal symptoms. Several approaches using dietary supplements have been investigated and some were found to be beneficial, but none have investigated the benefits of combining them together. The aim of this study is to assess the effectiveness of a proprietary formulation of ingredients which individually have been shown to relieve the most troublesome symptoms of the menopause. The supplement provides thiamine, riboflavin, pyridoxine, vitamin D, soy isoflavones, rosemary extract and krill oil, and was previously studied in PMS and found to be highly effective in terms of relieving symptoms similarly common in menopause, such as anxiety, fatigue, forgetfulness, insomnia and headache.

Who can participate?
Women aged between 45 and 59 with problematic menopausal symptoms

What does the study involve?
Participants take two capsules of the supplement each day with meals for 3 months, and are instructed not to make significant changes to their usual diet. Participants are asked to complete a questionnaire over each of the following 3 months of the study, and rank the impact of the menopausal symptoms they experience.

What are the possible benefits and risks of participating?
The benefits are that participants may experience an improvement in the troublesome symptoms of the menopause. The assessments of menopausal symptoms are not invasive. Krill oil has been demonstrated to be a completely safe form of Omega 3 supplementation. The herbs and vitamins which are also ingredients in this formulation have also been demonstrated to be safe. Because krill oil is derived from a crustacean, people with an allergy to shellfish were advised not to participate in the study. Those taking anticoagulants were not allowed to participate in this study.

Where is the study run from?
Talkhealth Partnership Ltd (UK)

When is the study starting and how long is it expected to run for?
February 2015 to September 2015

Who is funding the study?
Savant Marketing Ltd

Who is the main contact?
Michael Wakeman

Contact information

Type(s)
Scientific

Contact name
Mr Michael Wakeman

Contact details
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DE6 1LB

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Nat1

Study information

Scientific Title

An open label pilot study to evaluate the effectiveness of a proprietary krill oil formulation in the relief of troublesome symptoms of the menopause

Study objectives
The primary objective was to evaluate the effectiveness of a supplement in the management of menopausal symptoms. The study hypothesis was that it would significantly reduce the menopausal symptoms and be effective in their management. Primary outcome measure was based upon the scores of the self-assessment MRS questionnaire for symptoms at baseline compared to those at the end of each of the three months and the efficacy measures were assessed using the paired students t-test.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Because those receiving concurrent treatment for menopause were excluded, and since no new interventions were introduced during the course of the trial, and no personal data identifying any individuals was collected, the study did not meet the criteria necessitating approval from a UK Regional Ethics Committee. However, the protocol did meet the necessary requirements of the investigators' academic institution.

Study design
Prospective open-label evaluation

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Home

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Menopausal symptoms

Interventions
Each dose of the krill oil compound supplement contains thiamine hydrochloride 1.4mg, riboflavin 1.6mg, pyridoxine hydrochloride 2mg, standardised soy isoflavones 50mg-(S101), standardised rosemary extract (S102) 50mg in soft gelatin capsules containing 350mg of krill oil. 2 capsules were taken each day during the active phase of the trial.

Intervention Type

Supplement

Primary outcome measure
Symptom severity was assessed using a Menopause Rating Scale (MRS) which measures menopausal or climacteric symptoms in a standardized way and was validated some years ago. It aims to establish an instrument that measures health-related quality of life that can easily be completed. The original German scale has been translated into English and culturally adapted. Assessed at baseline, 1 month, 2 months and 3 months

Secondary outcome measures
Side effects of the intervention assessed at baseline, 1 month, 2 months and 3 months

Overall study start date
01/02/2015

Completion date
01/09/2015

Eligibility

Key inclusion criteria
1. Women aged between 45 and 59 years old
2. Presenting with a subjective complaint of problematic menopausal symptoms for a minimum of three days per week for a period of at least 3 months
3. Presence of: marked impaired daytime functioning, hot flushes, appetite loss, sleepiness, nausea, dizziness, tiredness, dry mouth, abnormal sweating, constipation, trouble sleeping, nervousness, mood changes, vaginal changes, urinary incontinence

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Female

Target number of participants
100

Key exclusion criteria
1. Evidence that menopausal symptoms are directly related to a severe or unstable medical disorder or severe psychiatric disorder (e.g.,bipolar disorder, schizophrenia)
2. Presence of sleep apnea or periodic limb movements during sleep
3. Presence of major depression or other severe psychopathology
4. Patients receiving HRT, clonidine, SSRI medications (antidepressants), Isoflavone containing supplements, Omega 3 or 6 supplements

Date of first enrolment
01/02/2015

Date of final enrolment
30/04/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Talkhealth Partnership Ltd
Landmark House
Station Road
Hook
United Kingdom
RG27 9LT

Sponsor information

Organisation
Total Health and Wellbeing Ltd

Sponsor details
The Orchards
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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Savant Marketing Ltd

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2016	15/10/2020	Yes	No