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Vasomotor symptoms (VMS) and endothelial function: A randomised placebo-controlled trial of oral micronised Progesterone (Prometrium ®)

Submission date
09/02/2005

Recruitment status
No longer recruiting

Registration date
10/05/2005

Overall study status
Completed

Last Edited
31/01/2014

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00152438

Study information

Scientific Title

Acronym
VMS Progesterone Study

Study objectives
1. Oral micronised progesterone (OMP) will decrease vasomotor symptoms (VMS) scores within-woman by about 75% compared with their baseline score and significantly more than placebo
2. Oral micronised progesterone will increase endothelium-dependent forearm blood flow by plethysmography within-woman over three months compared with no change on placebo
3. Oral micronised progesterone will significantly decrease blood pressure within woman compared with her baseline; there will be no change in the placebo group
4. Oral micronised progesterone will cause no within-woman change in weight, waist circumference, fasting cholesterol, HDL cholesterol, LDL or triglyceride levels compared with her own baseline and any changes in the placebo-treated women
5. Oral micronised progesterone and placebo will improve health related quality of life as documented by the Menopause-Specific Quality of Life Scale (MenQOL) and the SF-36 but the effect of progesterone will be significantly greater than that of placebo on both instruments

Protocol amendment as of 17/05/2006:
6. Oral micronised progesterone in healthy menopausal women will have effects on prothrombin fragments 1 + 2 and other markers of coagulation or fibrinolysis that are equivalent to but no worse than the effects of placebo
7a. Women stopping active therapy with OMP will show a significant increase in vasomotor symptoms compared to the last month of therapy
7b. Vasomotor symptoms will be no worse during the month of therapy discontinuation than they were in the baseline month
7c. Women in the placebo group will show no change in vasomotor symptoms between the baseline and the discontinuation month of the study

Please note that, as of 06/05/2009, the anticipated end date of this trial has been updated from 30/04/2007 to 31/10/2009.

Ethics approval required
Old ethics approval format

Ethics approval(s)
April 2006

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)

Treatment

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

Interventions
The women in this 4-month study are randomised to either the placebo or the oral micronised progesterone. The participants maintain a Daily Menopause Diary© during the period of the study to keep track of their vasomotor symptoms and other factors. Screening tests to rule out heart disease and diabetes include blood pressure and heart rate assessment, fasting blood glucose, cholesterol levels and electrocardiogram (ECG) measurement.

Interventions as of 17/05/2006:
The women in this 5-month study are randomised to either placebo or oral micronised progesterone. Participants maintian a Daily Menopause Diary© during the period of the study to keep track of their vasomotor symptoms and other factors and also to know if there is any change in symptoms when they come off the blinded therapy. Blood tests will be done to measure clotting factors in blood at the baseline and at the end of three months of blinded therapy. Screening tests to rule out heart disease and diabetes include blood pressure and heart rate assessment, fasting blood glucose, cholesterol levels and electrocardiogram (ECG) measurement.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Progesterone (Prometrium ®)

Primary outcome(s)
Current primary outcome measure as of 13/05/2009:
Vasomotor symptoms prospectively recorded during the first month compared with changes in months one, two, three and four of the trial

Previous primary outcome measures:
1. Vasomotor symptoms prospectively recorded during the first month compared with changes in months one, two, three and four of the trial
2. Forearm blood flow by plethysmography prospectively measured before and after three months of Oral micronised progesterone or placebo therapy
3. Clotting factors, fasting lipids, blood pressure, waist circumference and weight; these changes by Oral micronised progesterone and placebo will provide new and important therapy effects
4. Hormone-related and general quality of life measures using the standardised Menopause-Specific Quality of Life Scale, the SF-36 instrument and Daily Menopause Diary items related to sleep, mood and energy
5. Other cardiovascular markers including C-Reactive Protein (CRP) and Apolipoprotein B (ApoB)

Key secondary outcome(s))
Added as of 13/05/2009:
1. Forearm blood flow by plethysmography prospectively measured before and after three

months of Oral micronised progesterone or placebo therapy
2. Clotting factors, fasting lipids, blood pressure, waist circumference and weight; these changes by Oral micronised progesterone and placebo will provide new and important therapy effects
3. Hormone-related and general quality of life measures using the standardised Menopause-Specific Quality of Life Scale, the SF-36 instrument and Daily Menopause Diary items related to sleep, mood and energy
4. Other cardiovascular markers including C-Reactive Protein (CRP) and Apolipoprotein B (ApoB)

Completion date
31/10/2009

Eligibility

Key inclusion criteria
Women past menopause who are between one and ten years of their last menstrual period, not on any hormones for at least the past 6 months, experiencing hot flushes or night sweats and without any history or risk factors of heart disease (smoking, overweight, high lipid levels).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
Amendment to protocol as of 17/05/2006:
1. Any menstruation in the preceding year
2. History of hysterectomy without ovariectomy unless she is 60 years of age
3. Use of ovarian hormone therapy (estrogen, progestin, progesterone or androgen) in the preceding six months
4. Any risk factors for heart disease like smoker, high blood pressure, high cholesterol, diabetes, overweight, and history of angina or abnormal electrocardiogram (ECG)

Date of first enrolment
01/01/2003

Date of final enrolment
31/10/2009

Locations

Countries of recruitment
Canada

Study participating centre
Centre for Menstrual Cycle and Ovulation Research (CeMCOR)
Vancouver, BC
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Sponsor information

Organisation
Centre for Menstrual Cycle and Ovulation Research (CeMCOR) (Canada)

Funder(s)

Funder type
Charity

Funder Name
This study is independently funded, by donations to the Centre for Menstrual Cycle and Ovulation Research (CeMCOR).

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	21/01/2014		Yes	No