

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	<input type="checkbox"/> Prospectively registered
Registration date 10/05/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 31/01/2014	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00152438

Secondary identifying numbers

N/A

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet**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 maintain 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 measure

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)

Secondary outcome measures

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)

Overall study start date

01/01/2003

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

Age group

Adult

Sex

Female

Target number of participants

165

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)

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Sponsor type

Charity

Website

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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**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date**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