

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

<b>Submission date</b> 09/02/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 10/05/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 31/01/2014	<b>Condition category</b> 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)

**Sponsor details**

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**Sponsor type**

Charity

**Website**

<http://www.cemcor.ubc.ca>

## 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?
<a href="#">Results article</a>	results	21/01/2014		Yes	No