

## CeMCOR Peri-P participant post #2 Progesterone for Perimenopausal Night Sweats and Hot Flashes

### ***Why Are only Some Progesterone for Perimenopausal Hot Flush Results Significant?***

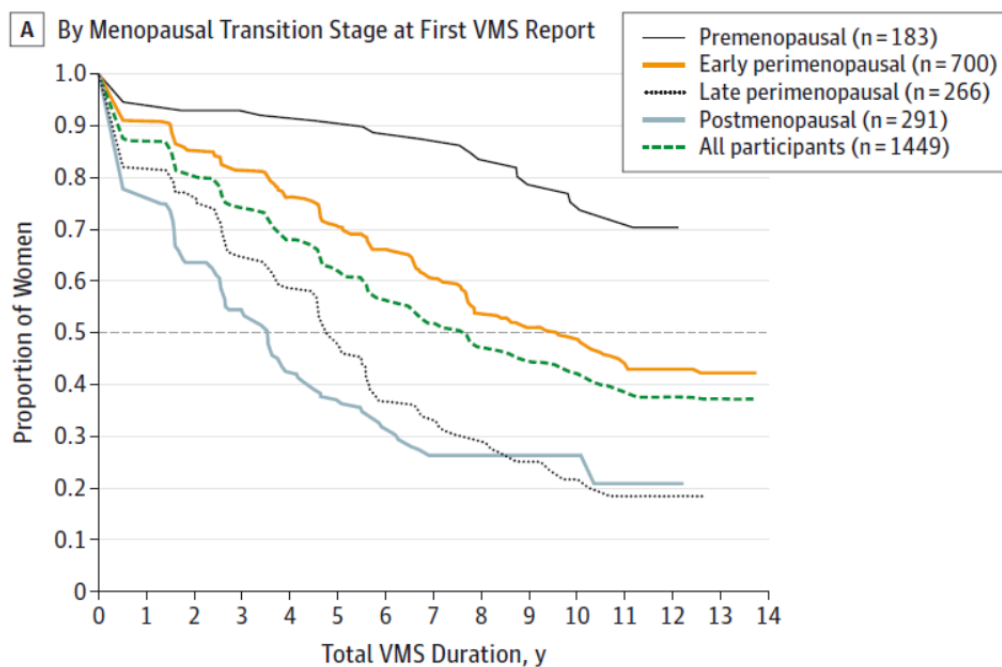
We likely got this result because, despite our best efforts, **we didn't study enough women.**

How many people are needed for a significant result in a randomized controlled trial? That depends on how variable the outcome being studied. **Perimenopause is, by definition, highly variable!**

Here are results from a study in the USA showing that women who start having hot flashes (Vasomotor Symptoms or VMS) when periods are still regular (the solid black line—here called “premenopausal” although CeMCOR would call these “very early perimenopause” <http://www.cemcor.ca/resources/how-can-i-tell-i-am-perimenopause>) have hot flashes lasting more than 12 years!.

If VMS only start once women have been a year without flow (blue line—called “postmenopausal” here) then they last about 3.5 years.

Finally it shows that the average length of time that hot flashes and night sweats last is about eight years (green line). What's interesting is that I was always taught that hot flashes lasted “a year or two.” This kind of study shows the value of research studying many women over a long period of time.



Nancy Avis *JAMA Internal Medicine*, 2015

**This is the first ever study of the treatment of hot flashes in women who are perimenopausal.**

Because no one has previously studied a treatment for hot flashes/night sweats **only in perimenopause**, we were making an educated guess about how many women we needed.

The first thing we did was to decide that we needed about 20% more women than the number (131) that we studied in the statistically significant study of “Progesterone for Menopausal Hot Flushes and Night Sweats Study” (Hitchcock CL, 2012 *Menopause*).

We further improved our *guess* about how many women we would need to study by doing a pilot study in 24 women over four months—we increased the number of women needed further.

Finally, after about half of the number of women we initially had planned to include had completed the study, we looked at the standard deviation (or the variability) of blinded results in their third month. Of course these results were in both women randomized to progesterone or to placebo. To keep the study accurate and scientific we did not break the code. We found we needed *twice as many women* as we had initially planned!

At that point in the trial we were running out of our grant money and the Data Safety and Monitoring Committee seemed to think that the trial was unlikely to find an answer. But, they did an important thing in helping us to get Health Canada to modify the requirement that all women have breast screening to only those with a personal or family breast cancer history. And that committee then agreed we could continue for a further year. Which we did and added about 50 more women.

I believe, despite not having quite enough women: **“Progesterone is *likely* effective for Perimenopausal Hot Flushes” and can be used now while larger studies are being performed.**

The other two therapies that are commonly prescribed for perimenopausal women with problematic hot flushes are:

- 1) the birth control pill (combined hormonal contraceptive or The Pill), or
- 2) menopausal hormone therapy (MHT)

Neither of these have come as close to be shown **effective** in perimenopause as we did with progesterone.

And both of these (unproven) therapies include giving **more estrogen** to perimenopausal women whose own estrogen levels are likely higher than normal. Therefore both The Pill and MHT likely carry higher risks for side effects than progesterone. With progesterone therapy we are “replacing” or supplementing the absent or low progesterone levels that are normal in perimenopause.

For these reasons, progesterone is also likely the **safest** of the potential treatments for perimenopausal hot flushes that we now have.