

# New device could more effectively alleviate menstrual cramp pain

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While most women experience minor pain during menstruation, for others, the pain can be severe enough to interfere with everyday activities and require medication. New research to be presented at the 2009 American Association of Pharmaceutical Scientists (AAPS) Annual Meeting and Exposition will reveal initial findings of safety surrounding a new device that may more effectively treat menstrual pain.

"The goal of our study was to find a better way to treat menstrual cramps," said Giovanni M. Pauletti, Ph.D., associate professor at the University of Cincinnati and the study's presenter as well as past chair of AAPS' National Biotechnology Conference Planning Committee.

"Existing oral medications cause significant gastrointestinal side effects for women, creating additional discomfort while alleviating menstrual pain. Results from our Phase I clinical trials show that this new vaginal device safely delivers at least 10-times more drug to the uterus as a tablet of equivalent dose."

The study, which was sponsored by UMD, Inc., a Cincinnati drug delivery company, and conducted at Women's Health Research, Inc. involved 18 study participants, aged 18-45 years with menstrual cycles between 25-30 days. During the mid-follicular phase of the first menstrual cycle (days 7-11), nine study participants received an oral dose of 10 mg of ketorolac (Toradol®), a non-steroidal anti-inflammatory medication; while nine women received a tampon coated with 10 mg of ketorolac. During the second menstrual cycle, each

subject received the opposite treatment.

The results of the study demonstrated that the medication administered vaginally does not cause significant side effects but accumulates more efficiently in the desired uterine tissue than using the oral medication.

"While still early in our research, this study shows promising results which may help pave the way for new treatment options for women," said Pauletti. "Phase II clinical trials will study efficacy of the treatment to assess whether the drug concentration is effective in reducing pain."

Source: American Association of Pharmaceutical Scientists

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