The Pill for Men? Phase 2 Clinical Data Suggest Hope for New Oral Contraceptive for Men

Dr. Dyan Pramesti of Airlangga University, Indonesia, presented preliminary clinical data which suggest that an orally administered plant extract from J. Gendarussa exerts a contraceptive effect through a novel mechanism, preventing the sperm and egg from joining – rather than stopping sperm production. Dr. Pramesti’s travel to the conference was supported by The Foundation for Male Contraceptives Inc., a non-profit organization headquartered in Durham, NC.

Atlanta, Georgia (PRWEB) April 04, 2014 -- Dr. Dyan Pramesti of Airlangga University, Indonesia, presented preliminary data from a Phase 2 clinical trial today (April 6, 2014) which suggest that (1) a plant extract from J. Gendarussa exerts a contraceptive effect through a novel mechanism – preventing the sperm and egg from joining – rather than stopping sperm production; and (2) a once-a-day oral dosage could potentially be as effective as women's oral contraceptives. The study, titled “A Study on Contraceptive Effect of Ethanol Extracted Justicia Gendarussa Burm. F. Leaves in Fertile Men,” was presented at the 39th Annual Meeting of the American Society of Andrology (ASA) http://andrologysociety.org/meetings/2014/.

The research conducted by the Indonesian team, led by Prof. Bambang Prajogo E.W. Ph.D. of the Dept. of Pharmacognosy and Phytochemistry, Faculty of Pharmacy, Airlangga University, Surabaya, Indonesia, is little known outside of Indonesia. Prof. Bambang began research on J. Gendarussa in 1987, based on ethnographic research conducted by the late Prof. Muso in Papua. Prof. Muso had discovered that rural villagers made a tea from the plant that reduced male fertility. While PBS reported on earlier research by the team in 2011, http://video.pbs.org/video/2060345484/, the team has not yet published their research in the English literature. Some information is available on a website devoted to male contraceptives, http://www.newmalecontraception.org/indonesian-pill-gendarusa/.

The presentation at the ASA meeting today was their first presentation of these results to a group of experts in male fertility and contraception. They are hopeful that meetings with US scientists will lead to collaborative research and funding to help get a Gendarussa extract approved by the Indonesian FDA, and subsequently get it approved for use in other countries.

Partial details of the study are as follows. The subjects were 350 healthy fertile men age 21-40 years, divided into two groups using a partially blinded, non-randomized design. Group one (186 men) took Gendarussa capsules daily for 30 days; group two (164 men) took placebo capsules and were instructed to use condoms. Semen analyses and sperm protein profiles were done before, during and after treatment. Men in the placebo group (164) were told to continue using condoms.

In the Gendarussa group, researchers found that sperm numbers and sperm motility were normal, but there was a disappearance of sperm protein bands at 38 kDa and 41,5 kDa after 5 days of treatment. The sperm protein bands returned to normal 30 days after stopping medication. Pregnancy results were promising. Since sperm numbers and motility were normal, the authors suggest that the Gendarussa extract acts by interfering with fertilization, i.e. preventing the egg and sperm from uniting. More complete details are being prepared for publication.
David C. Sokal, MD, who worked in clinical research on men’s reproductive health for 20 years, and is head of the Foundation for Male Contraceptives, commented that, “If confirmed, this could be an important advance in contraceptive technology, since most research on male methods has focused on halting sperm production by the testes, rather than interfering with sperm function. Based on the study results, the effectiveness of a Gendarussa extract could be similar to that of women’s oral contraceptives. However, additional research is needed to better define the extract’s safety and efficacy, and to clarify the mechanism of action.” Dr. Sokal added, “These results deserve attention from major funders such as the U.S. National Institutes of Health and The Bill and Melinda Gates Foundation.”

Prior to this Phase 2 clinical trial, Prof. Bambang and his team had conducted research on Gendarussa for over 20 years. They began with phytochemical screening to identify and isolate active agents, and continued with research in rodents, including toxicology, pharmacology, pharmacokinetics and bioavailability. In their preclinical studies, they confirmed the anti-fertility effect and did not see any serious adverse effects. Prior human research included a pharmacokinetic study and a Phase 1 study.

The ASA gave Dr. Pramesti a travel award to attend the conference, and the Foundation for Male Contraceptives provided additional financial support so that she and Prof. Bambang Prajogo E.W. Ph.D., and co-investigator Sri Musta’ina M.S. could attend the conference. Dr. Pramesti and Ms. Sri Musta’ina are both associated with the Reproductive Health Research Centre, School of Medicine, Airlangga University. Airlangga University has about 25,000 students and is one of the top five universities in Indonesia, [http://en.wikipedia.org/wiki/Airlangga_University](http://en.wikipedia.org/wiki/Airlangga_University). The Foundation for Male Contraceptives arranged for the researchers’ travel with support from the Parsemus Foundation.

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