November 2009 Medical Journal Article Describes Large Ongoing Study About Safety Of YAZ

INAS-OC Study: Intended To Evaluate Risk Of Developing Cardiovascular Side Effects For Women Who Use YAZ (DRSP/EE 24d)

(Posted by Tom Lamb at www.DrugInjuryWatch.com on November 24, 2009; see http://bit.ly/5zFC9L)

In May 2009 we first wrote about the International Active Surveillance Study of Women Taking Oral Contraceptives (INAS-OC Study), which is intended to evaluate the risk of developing cardiovascular side effects for women who use YAZ, a popular birth control containing a unique progestin, drospirenone (DRSP), and a relatively low dose of an estrogen, ethinylestradiol (EE). We reported, then, that this YAZ safety study had started in August 2005 and was ongoing as of May 2009.

We recently learned more about the current status of this INAS-OC Study in an article published November 18, 2009 by *BMC Medical Research Methodology*-- which is an open access journal publishing original peer-reviewed research articles in methodological approaches to healthcare research.

The November 2009 medical journal article about this ongoing YAZ safety study is called "International Active Surveillance Study of Women Taking Oral Contraceptives (INAS-OC Study)".

From the Abstract for this INAS-Study article we get this information:

> BACKGROUND: A 24-day regimen of contraceptive doses of drospirenone and ethinylestradiol (DRSP/EE 24d) was recently launched. This regimen has properties which may be beneficial for certain user populations (e.g., women suffering from premenstrual dysphoric disorder or acne). However, it is unknown whether this extended regimen has an impact on the cardiovascular risk associated with the use of oral contraceptives (OCs). The INternational Active Surveillance study of women taking Oral Contraceptives (INAS-OC) is designed to investigate the short- and long-term safety of the new regimen in a population which is representative for the typical user of oral contraceptives. Methods / Design A large, prospective, controlled, non-interventional, long-term cohort study with active surveillance of the study participants has been chosen to ensure reliable and valid results. More than 2,000 gynecologists in the US and 5 European countries (Austria, Germany, Italy, Poland, and Sweden) will recruit more than 80,000 OC users. The two to five year follow-up of these women will result in at least 220,000 documented women-years. The main clinical outcomes of interest for the follow-up are deep venous thrombosis, pulmonary embolism, acute myocardial infarction and cerebrovascular accidents....

We look forward to eventually seeing the results obtained from this INAS-OC Study, which is reportedly funded by an unconditional grant from Bayer Schering Pharma AG, Berlin.

Attorney Tom Lamb represents people in personal injury and wrongful death cases involving unsafe prescription drugs or medication errors. The above article was posted originally on his blog, **Drug Injury Watch** – with live links and readers' Comments.
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