

Merck Funded Study Says There Is No Blood Clot Risk With NuvaRing, While BMJ Medical Journal Article Reports A 90% Increased Risk

Perhaps These Conflicting Findings As Regards Serious NuvaRing Side Effects (PE, DVT, Stroke) Will Prompt FDA To Convene An Advisory Committee Meeting To Consider Safety Of This Vaginal Ring

(Posted by Tom Lamb at www.DrugInjuryWatch.com on May 16, 2012; see <http://bit.ly/L12ZOd>)

Some conflicting and rather disturbing data about the safety of Merck's NuvaRing vaginal ring birth control method emerged in early May 2012 from two different medical studies.

The first study -- for which the costs were reimbursed by Merck, the marketer of NuvaRing -- found no increased risk of venous thromboembolism (VTE) development between the combination contraceptive vaginal ring (NuvaRing) and combined oral contraceptives (COCs, or birth control pills).

The second study -- done by a set of independent researchers, *i.e.*, no support from any organization for the subject study -- had quite a different finding:

With an incidence of 7.8 confirmed events per 10 000 exposure years, the vaginal ring [NuvaRing] conferred a 90% higher risk of venous thrombosis than did combined oral contraceptives containing levonorgestrel, bringing the risk to the same level as that of combined oral contraceptives with third and fourth generation progestogens, and compatible with the Food and Drug Administration study [done by the FDA Office of Surveillance and Epidemiology in 2011, "[Combined hormonal contraceptives \(CHCs\) and the risk of cardiovascular disease endpoints.](#)" (PDF)]

Source: "[Venous thrombosis in users of non-oral hormonal contraception: follow-up study, Denmark 2001-10](#)", published May 10, 2012 by *BMJ* (free access).

First we will consider the Merck-funded study or trial, called the Transatlantic Active Surveillance on Cardiovascular Safety of NuvaRing, which was presented May 7, 2012 at the American Congress of Obstetricians and Gynecologists (ACOG) 60th Annual Clinical Meeting. We get this summary of the findings from a May 9, 2012 *MedPage* article (free registration required), "[No Increase in VTE Risk with Vaginal Ring](#)":

A large-scale study found no difference in venous thromboembolism (VTE) development between the combination contraceptive vaginal ring (NuvaRing) and combined oral contraceptives, researchers reported here.

Of the 34 VTEs that occurred in the 66,489 women-years of contraceptive use, the rate of VTE was 8.8 per 10,000 woman-years for the vaginal ring and 9.9 per 10,000 for combined oral contraceptives, a difference that was not statistically significant, according to Klaas Heinemann, MD, PhD, of the Center for Epidemiology and Health Research in Berlin, and colleagues.

Overall, use of hormone contraceptives resulted in a VTE rate of 9.4 per 10,000 woman-years, Heinemann said in his presentation at the annual meeting of the American College of Obstetricians and Gynecologists.

"Venous thromboembolism rates are similar for NuvaRing and combined oral contraceptives," Heinemann said. "A *twofold risk* of venous thromboembolism for

NuvaRing users compared to combined oral contraceptives *can be excluded.*" (emphasis added)

This "twofold risk" may or may not be a vague reference to the 2011 NuvaRing study done by the FDA, which we wrote about in an earlier article, "[NuvaRing Update: October 2011 FDA Study Finds Increased Risk Of Pulmonary Embolism \(PE\) And Deep Vein Thrombosis \(DVT\)](#)".

Next, we turn to the *BMJ* study, which adds to the evidence that women using the NuvaRing face higher thrombosis, or blood clots, risk than those taking oral contraceptives. Some of the findings by Danish researchers Øjvind Lidegaard, Lars Hougaard Nielsen, Charlotte Wessel Skovlund, and Ellen Løkkegaard are set forth in a May 10, 2012 *HealthDay News* article, "[Blood Clot Risk Linked to Some Non-Pill Contraceptives](#)":

For women who did not use any type of hormonal contraceptive, two women developed clots for every 10,000 (combined) years they used contraceptives.

For women taking the pill containing the hormone levonorgestrel, the risk for a clot was three times higher, or 6.2 clots for every 10,000 years they took the pill, the researchers found.

The risk to women who used a skin patch [Ortho Evra] was about eight times higher, or 9.7 clots per 10,000 exposure years.

Women who used a vaginal ring [NuvaRing] had a 6.5 times higher risk, or 7.8 events per 10,000 exposure years.

Of course we will continue to watch for more medical research and trials concerning the safety of Merck's NuvaRing birth control product, especially the possible continuation of the FDA NuvaRing safety study which was done in 2011, as mentioned above.

And, perhaps these conflicting findings about NuvaRing side effects -- like pulmonary embolism (PE) and deep vein thrombosis (DVT), as well as strokes and heart attacks -- will be presented by the FDA to its Reproductive Health Drugs and Drug Safety and Risk Management advisory committees at a joint meeting - similar to what was done in December 2011 for the controversial YAZ and Yasmin birth control pills.

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.
<http://www.DrugInjuryWatch.com>