

## The Drospirenone Controversy

You may have heard recent publicity about certain birth control pills and their risks. The information below is provided to help explain the issue.

Drospirenone is a type of female sex hormone called a progestin. Most oral contraceptives, or birth control pills contain two types of hormones- an estrogen and a progestin. Birth control pills prevent the release of eggs from the ovaries and change the cervical mucus and lining of the uterus. These pills are prescribed to prevent pregnancy, but they are also used for many other reasons including but not limited to irregular menstrual cycles, painful menstruation, acne, PMS, endometriosis and polycystic ovarian syndrome. Brand names of drospirenone-containing pills include Yaz (generics Gianvi and Loryna), Yasmin (generics Ocella, Syeda and Zarah), BeYaz and Safyral.

In the past several years, studies have been done to compare the safety of drospirenone-containing birth control pills to other birth control pills, which contain a progestin called levonorgestrel. Specifically, studies have looked at the risk of blood clots- deep venous thrombosis (VTE), blood clots in the legs and pulmonary embolism, blood clots in the lungs\*. These studies have shown mixed results and led to confusion about safety.

Two studies published in 2007 reported that drospirenone-containing birth control pills did not significantly increase the risk of VTE. Two studies which came out in 2009 and two more studies in 2011 have suggested that drospirenone-containing pills do increase the risk of VTE. Unfortunately, none of the published studies are perfect. In order to be scientifically useful, studies should assess and control other risk factors and variables that might affect their outcomes. None of the studies were completely able to do this.

The results of the present research are inconsistent. If there is an increased risk of VTE with drospirenone-containing birth control pills, it is thought to be quite small (i.e. 10 in 10,000 users with drospirenone-containing pills versus 7 in 10,000 users with other progestin-containing pills). **All birth control pills regardless of their specific estrogen and progestin content have a risk of VTE.** This is called a “class effect” of these drugs. In women under the age of 35 who are healthy and without specific risk factors for VTE, the risk of VTE is very low. The risk of VTE associated with any birth control pill use is much smaller than the risk of VTE in a normal pregnancy.

The risks and benefits of drospirenone-containing birth control should be considered in light of your particular risk for developing blood clots. Factors associated with an increased risk of VTE include smoking, being overweight and having a family history of VTE. If you are taking a drospirenone-containing birth control pill, you should continue taking it as directed. Your physicians are very comfortable in continuing to recommend and prescribe drospirenone-containing birth control pills.

The U.S. Food and Drug Administration recently reported that the benefits of drospirenone-containing birth control pills outweigh the risks. Studies addressing VTE risk will be ongoing. If you have questions or concerns regarding your birth control pill and its risks, please consult with your physician.

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\*The most common signs and symptoms of VTE include swelling or pain in the leg, warmth and/or change in color of the skin on the leg and sudden shortness of breath or chest pain. It is important to seek medical attention immediately if you experience any of the above.