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Study: Yaz Has Higher Risks of Blood Clots

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A new study of 1.3 million Danish women over nine years adds to the evidence that some newer birth-control pills, including the best-seller Yaz, have a higher risk of causing potentially dangerous blood clots.

Newer pills containing drospirenone, a synthetic hormone, were linked to a six-fold increase in the risk of venous thromboembolism, which is the formation of clots in the lower leg or thigh that can break loose and travel to the lungs.

That risk was compared with a three-fold increase in women using older contraceptives containing the synthetic hormone levonorgestrel. [The study](#) was published Tuesday on the Web site of BMJ, formerly known as the British Medical Journal.

A BMJ editorial added, “It is crucial, however, not to exaggerate the risk — oral contraceptives are remarkably safe and may confer important long-term benefits in relation to cancer and mortality.”

The Food and Drug Administration is already [studying the possible increased risk](#) of blood clots with pills containing the drospirenone. The F.D.A. says its preliminary results suggest a 1.5-fold increased risk compared with other hormonal contraceptives, to about 10 women in 10,000 from 6 women in 10,000.

Studies have differed, though. Some found no increased risk among women taking the newer pills. The F.D.A. has scheduled a joint meeting of two advisory committees on Dec. 8 to review the risks and benefits.

Bayer, the German drug company that makes Yaz and the related product Yasmin, has said the two have similar clot risks to other combination birth control pills, including levonorgestrel. The company updated its labels last year with that indication.

The new study, sought by the European Medicines Agency, challenges that finding.

Bayer, in a brief statement Wednesday, said it is “currently evaluating this publication and cannot comment at this time.”

Bayer also said its clinical data from more than 15 years supports the company’s assessment that its hormonal birth control products are safe and effective when used as indicated and that the risk of venous thromboembolism is similar to that from taking any other low-dose estrogen product studied.

Thousands of women have sued Bayer, contending that they have suffered injuries from taking Yaz or Yasmin. Bayer introduced Yasmin in 2001 and Yaz in 2006. Yaz contains the same amount of drospirenone but a smaller amount of ethinylestradiol, a synthetic estrogen commonly paired with progestins in birth control pills.

The Danish study found essentially no difference in the risk of venous thromboembolism between Yaz and Yasmin, and in both cases, about double that of some other hormonal birth control pills.

Some of the numbers were small, though. The study found 23 reported events of venous thromboembolism in the Yaz group, confirming 16 of them with medical records, compared with 78 reported events, confirming 57 of them, for users of older levonorgestrel. The latter group was more than four times larger than the Yaz group. That left levonorgestrel with more certainty about a relative risk of the clot of two to four times that of nonusers, while Yaz had a wider range of risk, four to 11 times that of nonusers, within statistical significance, the study said.

The researchers estimated 2,000 women would need to change birth control pills to prevent one incident of venous thromboembolism in a year.

[Yaz has been marketed](#) and F.D.A. approved for quality of life treatment for acne and severe premenstrual symptoms, in addition to birth control benefits. The drugs have had worldwide sales of \$1.47 billion last year.

Yaz sales in the United States declined earlier this year, the company said, blaming generic competition.