

Hormone therapy does not increase risk of recurrent venous thromboembolism in women who are on full-dose anticoagulation

Question

In women with venous thromboembolism (VTE) on full-dose anticoagulation, does hormone therapy increase the risk of recurrent VTE compared with no hormone therapy?

The study

Who? The study included 1888 women who were treated for acute symptomatic deep vein thrombosis or pulmonary embolism with enoxaparin plus a vitamin K antagonist or rivaroxaban as part of the EINSTEIN DVT/PE randomized clinical trials.

What? The study compared the risk of recurrent VTE in women on full-dose anticoagulation who were taking hormone therapy versus those who were not taking hormone therapy.

Hormone therapy*	vs	No hormone therapy*
Hormone therapy included estrogen-only pills, combined estrogen-progesterone contraceptives, and progestin-only contraceptives (including pills, implants, injectables, and intrauterine devices).		No hormone therapy.

*All women were on full-dose anticoagulation with enoxaparin plus a vitamin K antagonist or rivaroxaban.

What the researchers found

The rate of recurrent VTE did not differ in women who continued or started hormone therapy compared with women who were not on hormone therapy.

The bottom line

In women who are fully anticoagulated for VTE, hormone therapy did not increase risk of recurrent VTE.

Summary of findings

Hormone therapy vs no hormone therapy in women who are on full-dose anticoagulants for VTE

Outcomes at 3 to 12 months	Rate of events with hormone therapy	Rate of events with no hormone therapy	Absolute effect of hormone therapy
Recurrent VTE	4 out of 100 women per year	5 out of 100 women per year	No effect*

*Although the rates for the 2 groups look different, the differences were not statistically significant—this means that the difference could simply be due to chance rather than due to the different treatments.

This Evidence Summary is based on the following study:

Martinelli I, Lensing AW, Middeldorp S, et al. **Recurrent venous thromboembolism and abnormal uterine bleeding with anticoagulant and hormone therapy use.** *Blood.* 2016 Mar 17;127(11):1417-25. PubMed (<https://www.ncbi.nlm.nih.gov/pubmed/26696010?dopt=Abstract>)

No need to stop hormone therapy in women who are taking full-dose anticoagulation

Hormone therapy, in the form of oral contraceptive therapy or as replacement therapy for menopause, increases the risk of venous thrombosis. For this reason, it is common for women with VTE to be told they must immediately stop hormone therapy. Although well-intended, there are several potential negative consequences to this advice:

- increased risk of fetal anomalies if a woman becomes pregnant while on anticoagulant therapy;
- increased risk of an unwanted pregnancy (other methods of contraception can be more burdensome and less reliable); and
- increased risk of menorrhagia in women who were taking hormone therapy to control this problem.

These risks might be worth accepting if we knew that continuing hormone therapy was harmful in women with VTE. However, the post hoc analysis of VTE treatment studies summarized above provides reassurance that continuing hormone therapy does not increase the risk of recurrent VTE. Instead, anticoagulant therapy likely suppresses the prothrombotic effect of hormones.

Doctor, do I have to stop taking my birth control pills because I have a blood clot?

No, not if you are on blood thinners and are taking them properly. However, when it is time for you to stop blood thinners, we will need to talk again about the risks versus benefits of hormone therapy because you will no longer have the protection of blood

thinners.

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Glossary

anticoagulant	medications that prevent blood clots from forming or travelling (aka blood thinner)
anticoagulants	medications that prevent blood clots from forming or travelling (aka blood thinner)
anticoagulation	medications that prevent blood clots from forming or travelling (aka blood thinner)
deep vein thrombosis	formation of a blood clot within a vein deep within the leg
pulmonary embolism	blood clot(s) that cause obstruction of blood vessels within the lungs (pulmonary artery), after travelling from veins, most commonly within the leg or arm or pelvis
rivaroxaban	Xarelto® (aka DOAC)
venous thromboembolism (VTE)	the collective term referring to blood clots within the veins, most commonly deep vein thrombosis and pulmonary embolism
VTE	venous thromboembolisms; collective term referring to blood clots within the veins