

## Tibolone and cancer recurrence

Women treated with adjuvant therapy for breast cancer often experience vasomotor symptoms and bone loss as complications. The synthetic steroid, tibolone, is used to prevent these adverse effects but whether it affects cancer recurrence is unknown. Kenemans and colleagues carried out a noninferiority study to investigate the effect of tibolone on breast cancer recurrence in patients with climacteric symptoms and found that tibolone increases the risk of recurrence while preventing bone loss and vasomotor symptoms.

This multinational trial included 3,098 women with vasomotor symptoms and a history of breast cancer. Patients were randomly allocated to receive either 2.5 mg daily of tibolone or placebo. The primary end point was breast cancer recurrence and analysis was by intention to treat. The mean age of the patient at randomization was 52.7 years. After a median follow-up period of 3.1 years, 15.2% of women who received tibolone experienced recurrence compared with

10.7% of patients who received placebo.

“It is well known that in breast cancer, micrometastases may lie dormant somewhere in the body and can start to grow even after 10, 15 or 20 years. Our results indicate that tibolone reactivates these dormant metastases earlier than without tibolone,” said Kenemans.

There was no difference between tibolone and placebo with regard to safety outcomes such as mortality, cardiovascular events or gynecological cancers. As shown in previous studies, vasomotor symptoms and bone-mineral density improved significantly with tibolone compared with placebo. The authors concluded that “all future research should be directed to find other ways of alleviating severe climacteric symptoms. Probably these approaches have to be nonhormonal.”

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