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FALCON: A phase III randomised trial of fulvestrant 500 mg vs. anastrozole for hormone receptor-positive advanced breast cancer

[M.J. Ellis](#), [I. Bondarenko](#), [E. Trishkina](#), [M. Dvorkin](#), [L. Panasci](#), [A. Manikhas](#), [Y. Shparyk](#), [S. Cardona-Huerta](#), [K-L. Cheung](#), M.J. Philco-Salas ..

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Background: This Phase III, randomised, double-blind, multicentre trial (FALCON; NCT01602380) compared the selective estrogen receptor (ER) degrader (SERD) fulvestrant with anastrozole in patients with ER- and/or progesterone receptor-positive locally advanced or metastatic breast cancer who had not received prior hormonal therapy.

Methods: Patients were randomised 1:1 to fulvestrant (500 mg IM on Days 0, 14, 28, then each 28 days) or anastrozole (1 mg daily). The primary endpoint was progression-free survival (PFS), assessed via RECIST 1.1, surgery/radiotherapy for disease worsening, or death. Secondary endpoints were: overall survival (OS); objective response rate (ORR, complete response [CR] or partial response [PR]); duration of response (DoR); expected DoR (EDoR); clinical benefit rate (CBR; CR, PR, or stable disease ≥24 weeks); duration of clinical...

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