Fakultät für Medizin

Dokumenttyp: journal article

Autor(en) des Beitrags:
Cuzick, Jack; Sestak, Ivana; Forbes, John F; Dowsett, Mitch; Knox, Jill; Cawthorn, Simon; Saunders, Christobel; Roche, Nicola; Mansel, Robert E; von Minckwitz, Gunter; Bonanni, Bernardo; Palva, Tiina; Howell, Anthony; IBIS-II investigators; Bonanni, Bernardo; Buchanan, Mary; Bundred, Nigel; Cawthorn, Simon; Coleman, Robert E; Cuzick, Jack; Dowsett, Mitch; Eastell, Richard; Ejlertsen, Bent; Ellis, Ian; Forbes, John F; Howell, Anthony; Kahan, Zsuzsanna; Leonard, Gerry; Levy, Christine; Mansel, Robert E; Marshall, Jennifer; Neven, Patrick; Palva, Tiina; Rukazenkov, Yuri; Rydén, Lisa; Senn, Hans-Jorg; Sestak, Ivana; Stierer, Michael; Vaz, Fatima; von Minckwitz, Gunter; Abdil, Ehtesham; Aktas, Bahriye; Artioli, Fabrizio; Augustin, Doris; Baker, Caroline; Beckmann, Matthias; Bennett, Ian; Bertelli, Gianfilippo; Blum, Robert; Bolliger, Barbara; Bonanni, Bernardo; Boyce, Adam; Bradpiece, Howard; Bramley, Maria; Breitbach, Georg-Peter; Brincat, Stephen; Briscoe, Karen; Buchholz, Olaf; Buser, Katharina S; Bucher, Susanne; Campbell, Ian; Carmalt, Hugh; Cawthorn, Simon; Bristol, James; Chappuis, Pierre O; Clark, David; Coleman, Robert E; Collins, John; Conrad, Bettina; Costa, Serban-Dan; Daoud, Raouf; Della-Fiorentina, Stephen; Deryal, Mustafa; Donovan, Michael; Drew, Philip; Dubey, Sidharth; Ellenbogen, Simon; Evoy, Denis; Federico, Massimo; Ferguson, Douglas; Forbes, John F; Fox, John N; Gamboa, Jorge; Garne, Jens Peter; Gebski, Val; Gendy, Raafat; Graiff, Claudio; Gill, Peter Grantley; Gross, Sabine; Gupta, Rajnish; Gutteridge, Eleanor; Hamed, Hisham; Hanusch, Claus A; Hans-Jorg, Senn; Harding-McKean, Claudia; Heinrich, Georg; Hill, Jane; Hill, Arnold; Hoffmann, Gerald;
Anastrozole for prevention of breast cancer in high-risk postmenopausal women (IBIS-II): an international, double-blind, randomised placebo-controlled trial.

Abstract:
Aromatase inhibitors effectively prevent breast cancer recurrence and development of new contralateral tumours in postmenopausal women. We assessed the efficacy and safety of the aromatase inhibitor anastrozole for prevention of breast cancer in postmenopausal women who are at high risk of the disease. Between Feb 2, 2003, and Jan 31, 2012, we recruited postmenopausal women aged 40-70 years from 18 countries into an international, double-blind, randomised placebo-controlled trial. To be eligible, women had to be at increased risk of breast cancer (judged on the basis of specific criteria). Eligible women were randomly assigned (1:1) by central computer allocation to receive 1 mg oral anastrozole or matching placebo every day for 5 years. Randomisation was stratified by country and was done with blocks (size six, eight, or ten). All trial personnel, participants, and clinicians were masked to treatment allocation; only the trial statistician was unmasked. The primary endpoint was histologically confirmed breast cancer (invasive cancers or non-invasive ductal carcinoma in situ). Analyses were done by intention to treat. This trial is registered, number ISRCTN31488319. 1920 women were randomly assigned to receive anastrozole and 1944 to placebo. After a median follow-up of 5·0 years (IQR 3·0-7·1), 40 women in the anastrozole group (2%) and 85 in the placebo group (4%) had developed breast cancer (hazard ratio 0·47, 95% CI 0·32-0·68, p<0·0001). The predicted cumulative incidence of all breast cancers after 7 years was 5·6% in the placebo group and 2·8% in the anastrozole group. 18 deaths were reported in the anastrozole group and 17 in the placebo group, and no specific causes were more common in one group than the other (p=0·836). Anastrozole effectively reduces incidence of breast cancer in high-risk postmenopausal women. This finding, along with the fact that most of the side-effects associated with oestrogen deprivation were not attributable to treatment, provides support for the use of anastrozole in postmenopausal women at high risk of breast cancer. Cancer Research UK, the National Health and Medical Research Council Australia, Sanofi-Aventis, and AstraZeneca.