In the randomized phase III study (BOLERO-2 study) among patients with estrogen receptor (ER)-positive advanced breast cancer, the progression-free survival in the everolimus plus exemestane group was significantly longer compared with the exemestane group.

As an adverse drug reaction to everolimus, all-grade oral mucositis was reported in 58% of patients and 81% of Asian patients.

Methods

To examine whether the occurrence of oral mucositis can be reduced by appropriate oral management in patients after instruction from dental or oral surgeons provided to an observation group in a randomized, controlled study of women undergoing treatment with everolimus for estrogen receptor-positive (ER+), hormone therapy-resistant refractory breast cancer.

Eligibility criteria

• Postmenopausal women with hormone receptor-positive (HR+), metastatic breast cancer.
• Resistance to aromatase inhibitor therapy

No more than one prior chemotherapy treatment (anti-neoplastic drugs) since the diagnosis of metastatic or recurrent breast cancer

Study endpoints and analyses

Primary endpoint:

• Incidence of all-grade oral mucositis (CTCAE ver.3.0) after everolimus treatment (evaluated by an oncologist).

Secondary endpoints:

• Incidence of each grade of oral mucositis (evaluated by an oncologist and/or oral surgeon).
• Time to onset of oral mucositis.
• Duration of each grade of oral mucositis.
• Health-related quality of life (HRQOL).
• Time to treatment failure (TTF).

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