AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: DUMMY
ACTIVE INGREDIENT: DUMMY

Study No: NIS-OSI-DUM-2008/1
An open label non-interventional evaluation of the effect of adjuvant hormonal treatment of postmenopausal women wih early breast cancer with aromatase inhibitors on bone mineral density and bone fracture rate in daily practice

Developmental Phase: POSTMARKETING, NON-INTERVENTIONAL STUDY
Study Completion Date: 30/06/2009
Date of Report: 14/06/2010

OBJECTIVES:

Primary objective
To determine the effect of AI therapy on BMD as measured by DEXA scan and compare it to the effects of tamoxifen and no hormonal therapy (hormone-independant group).

Secondary objective
To determine the bone fracture rate in women on AI therapy and compare it to fracture rates observed in the tamoxifen and compare the results with the hormone-independant group.

METHODS:

Participating women were allocated to respective arms based on the characteristics of their disease and/or therapy that had already been prescribed for them. All women were treated at the Institute of Oncology Ljubljana, BMD measurements were be performed at the Clinical department for rheumatology, Peter Drzaj Hospital, Ljubljana. The primary studied variable was T value which is calculated as a ratio of the measured BMD and the reference mean value for Caucasian women agen 20-29 years. In addition, the number of fractures were observed.

In our case the statistically needed sample size was 64 women per group.

Inclusion criteria

The included patients had to be willing to sign the Informed consent form prior to inclusion to the NIS. All women diagnosed with hormone-dependant and hormone-independent early breast cancer and for which an adjuvant hormonal therapy had been prescribed in line with the relevant licence and additionally fulfilled the below criteria were enrolled into this NIS:

- Women to whom BMD was measured after chemo- and/or radiotherapy conclusion and before the potential start of adjuvant hormonal therapy:
    - Age between 55 and 65 years,
    - Surgery, chemo- and/or radiotherapy concluded less than 6 moths,
- Women with hormone-independent breast cancer:
    - Age between 55 and 65 years,
    - Surgery, chemo- and/or radiotherapy concluded before 24-36 months and 54-66 months, respectively,
- Women with hormone-dependant breast cancer:
    - Age between 55 and 65 years,
    - Adjuvant therapy with tamoxifen initiated before 24-36 and 54-66 months, respectively OR
    - Adjuvant therapy with AI initiated before 24-36 and 54-66 months, respectively OR
    - Switch from tamoxifen to AI initiated before 24-36 months.

Each woman could be enrolled only once.

Exclusion criteria

Women diagnosed with osteoporosis at the time of their breast cancer diagnosis and receiving active treatment for this condition were not eligible for this NIS. Women with any evidence of breast cancer recurrence were not eligible for this NIS.

RESULTS:

Only 117 patients were included into the study which was not enough to perform the planned statistical analysis.

The average age of the patients was 60 years. In 27 patients (23%) osteoporosis was diagnosed. In patients treated with aromatase inhibitors there was a trend to a lower BMD in lumbar spine compared to tamoxifen group, but the groups were too small for statistical comparison.

AZ Synopsis Template 2010 June 4