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Objective:

The double blind, placebo-controlled study was performed to determine whether Korea's Apixel Co., Ltd.'s micronized calcium/NC-518® increased the bone mineral density as compared to that of Pfizer's Caltrate.

Procedure:

The NC-518 Human Clinical Study was performed at Friends Medical Group, Anaheim, CA, from April 2010 to December 2010. Total 49 Participants qualified for the study and were randomly divided into either NC-518 or Caltrate group. The groups were also subdivided into bisphosphonate and non-bisphosphonate group based on whether participants were on bisphosphonate medication. Baseline bone density of Lumbar and Femoral bone was measured and after consumption of calcium, bone density test was repeated. Comparative analysis was performed.

Results:

1. Average T-Score increase or decrease in the Bisphosphonate and Non-bisphosphonate groups **combined** between NC-518 and Caltrate was **+0.19 and 0.00**, respectively.
2. Average T-score improvement in the **Bisphosphonate** group was **+0.19 (about 2.2%)** for NC-518 group while that of Caltrate was **0 or no change**.
3. Average T-score increase/decrease in the **Non-bisphosphonate** group was **+0.16 (about 2%)** for NC 518 group while that of Caltrate was **-0.11 (-1.1%)**.

Note: 1 SD difference in a T-score is equal to a 10-15% difference in bone density. For example, a person with a T-score of -2.5 has a 10-15% lower BMD than a person with a T-score of -1.5. Based on this calculation, the following can be stated.

1 SD difference in T-Score = about 12.5%
0.06=0.34%, 0.1=1.13%, 0.2=2.25%

The analysis of 49 participants showed significantly more participants having improvement in the bone mineral density with NC-518 compared to that of Caltrate®, both in participants who were taking bisphosphonates and in participants who only took calcium (non-bisphosphonates). The P-Value was <0.05.

Average improvement in the bone mineral density score was also significantly higher in participants who consumed NC-518 compared to Placebo/Caltrate.

A larger study is recommended to reaffirm the test results.

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