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Objective:
The double blind, placebo-controlled study was performed to determine whether Korea's Apexel 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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Objective;
The double blind, placebo-controlled study was performed to determine whether Korea's Apexel Co., Ltd.'s micronized calcium/NC518 increased the bone mineral density as compared to that of Pfizer's Cultrate.

Procedure;
The NC-518 Human Clinical Study 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**

목적;
한국의 에이펙셀이 제조한 미크론 사이즈의 NC518칼슘이 파이자의 칼슘 제품인 Caltrate와 비교하여 골밀도를 증가시키는지를 확인하기 위하여 placebo 조정된 이중 맹검(二重盲檢) 연구를 수행하였습니다.

진행;

2010년 4월부터 2010년 12월까지 캘리포니아 Anaheim 시에 있는 Friends Medical Group에서 인체 임상시험을 이행했습니다. 임상시험 유자격 참여자는 총 49명이었으며 무작위로 NC-518 또는 Cultrate 복용군으로 2그룹으로 나누었습니다. 그리고 다시 골다공증 치료제재인 비스포스포네이트의 복용 여부에 따라 비스포스포네이트 군과 비 비스포스포네이트 군으로 나누었습니다. 요추와 대퇴부의 기준치를 측정했고, 칼슘 복용 후에 골밀도 측정 실험을 반복했습니다. 비교분석이 이루어졌습니다.

결과;
1. 비스포스포네이트 그룹과 비 비스포스포네이트 그룹에서 NC-518과 Cultrate 복용 간의 평균 T-score 증감

between NC-518 and Calttrate 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%).**

은 **+0.19** 과 **0.00**으로 나타났습니다.

2. 비스포스포네이트 그룹이 NC-518을 복용한 경우 평균 T-score 개선 수치는 **+0.19 (약 2%)** 였으나 Caltrate를 복용한 경우는 **0**으로 변화가 없었습니다.
3. 비 비스포스포네이트 그룹이 NC-518을 복용한 경우 평균 T-score 증감수치는 **+0.16 (약 2%)** 이었으나 Caltrate를 복용한 경우는 **-0.11 (약 -1.1%)**이었습니다.

Note: 1SD 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.

주: T-score에서 1 편차의 수치는 골밀도 10~15%와 동일함. 예컨대, T-score -2.5의 환자는 T-score -1.5의 환자보다 골밀도가 10-15% 낮음. 이에 기초하면 다음과 같은 산출수치가 형성됨.

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

T-score에서 편차수치 차이
1의 차이 = 약 12.5%
0.06 의 차이 = 약 0.34%
0.1 의 차이 = 약 1.13%
0.2 의 차이 = 약 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.

임상시험 참여인원 49명 중 비스포스포네이트를 복용하던 혹은 칼슘만을 복용용하던 (비 비스포스포네이트) 상관 없이 NC-518을 복용한 그룹이 Caltrate를 복용한 그룹과 비교하여 더 많은 환자들의 골격에서 괄목할만한 골밀도 T-score 개선 수치를 보였습니다.
P-Value는 0.05였습니다.

Average improvement in the bone mineral

NC-518을 복용한 임상시험 참여인원 그

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.

룹의 골밀도 개선 평균치가 Placebo/Caltrate를 복용한 그룹과 비교하여 괄목할 만큼 높았습니다.
동 실험결과를 재확인 하기 위하여 대규모의 임상연구가 권고됩니다.

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