Randomized placebo controlled trial to determine the placebo effect size in orthopaedic

Authors:
L. Gerdesmeyer, H. Vester, M. Henne

Institution:
Technical University Munich

Dept. of Orthopedic Surgery and Sportstraumatology
Ismaninger Str. 22, D-81675 München

Introduction:
The aim of the trial was to detect the placebo effect size in orthopaedic

Methods:
First step was a complete literature search to find out relevant parameters. 2nd step was to complete a feasibility study to verify published data. In the 3rd step we designed the trial in accordance to GCP E6 and E4 guidelines with power calculation, sample size calculation, etc..
106 patients, suffering from chronic shoulder or heel pain received shame extracorporeal shock wave treatment after written informed consent. Randomly 52 patients was told to get the real therapy and 53 to get the shame treatment. The primary criteria was the subjective outcome on the visual analogue scale, the secondary criteria the Roles and Maudsley score. The primary end point was 1 month after treatment

Results:
Both groups showed a decrease on the VAS. Patients who know to be in the placebo-group decreased with 6% from 6.7 to 6.3 [95% CI: 0,4 .. 11,1]. Patients who believed to be in the "real" group decrease with 21% [95% CI:13,3 .. 27,7] from 7.0 to 5.5. The same effect was also shown in the Roles and Maudsley Score. Retrospective analysis showed effective randomisation and blinding technique.

Discussion and Conclusion:
The placebo effect is very important in orthopaedic treatment methods. The effect size reaches clinical relevance and must be discussed and controlled in every clinical study.