Abstract:

BACKGROUND: The bloodletting device has been used by many institutions for about 100 years. Many patients feel fear from the pain caused by applying the bloodletting device for treatment. We used bloodletting device using the principle of “prestimulation neurodisturbance,” which can mask the subject undetectable for pain. In this study, we will investigate pain of bloodletting device during blood collection and will identify the safety of the device.

METHODS: This study will be a randomized, controlled, double-blind, and matched-paired-designed clinical trial. Four groups, RTLC, LTRC, RCLT, and LCRT (T = test device, C = control device, L = left, R = right), will be randomly allocated. Total duration of the clinical trial will be 3 months. The subjects will be performed from 1 to 3 times only on the day of the procedure. The primary outcomes will be measured using pain visual analog scale score and the secondary outcomes will include verbal rating scale and the time at which the pain disappears after blood collection (second), the total number of “nonbleeding” cases and subjects, the number of “blood collection failure” and subjects, the presence of “delayed hemostasis,” and the number of subjects. Repeated-measure analysis will be used to measure primary efficacy based on full analysis set.

DISCUSSION: This study has limited inclusion and exclusion criteria and a well-controlled intervention, and it will be the first randomized controlled trial to investigate pain of bloodletting device using the principle of “prestimulation neurodisturbance.” This study provides insights into the underlying mechanisms of the pain-reducing effect of the developed bloodletting device and will lay the groundwork for further studies.

Reference:

Ryu, H.Y. and Kang, J.H. (2020) Pain assessment of a new bloodletting device: A study protocol for a randomized, controlled, double-blind, matched-paired clinical trial. Medicine. 99(5), p.e18705. doi: 10.1097/MD.0000000000018705.

Full Text