

Abbreviated Clinical Study Report

**Open-label, prospective clinical trial to evaluate the impact
on quality of life in Chronic Venous Insufficiency subjects
using SANKOM[®] Functional Patent Socks**

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Study Summary

The SANKOM® Functional Patent Socks have a conventional overall shape, and an over-the-calf sock intended to cover the wearer's foot and some to all of the wearer's calf. The principle of compression therapy is to exert a controlled pressure on the limb. The pressure unit is the millimetre of mercury (mmHg) or the hecto Pascals (hPa). 1 mmHg = 1.33 hPa. The SANKOM® Functional Patent Socks are class I medical devices. They may be used during travel and flights, during extended sitting periods, during extended standing periods, during pregnancy, in case of puffiness of the legs, during fitness and exercise, during long walking periods, or for any other medical reason.

Study Purpose and Design

Within the given clinical study, the SANKOM® Functional Patent Socks (international Patent app. PCT No. US 2017/032256) were analyzed. Multi-centre, the observational open-label study aimed to evaluate an impact on quality of life in Chronic Venous Insufficiency subjects using SANKOM® Functional Patent Socks for 30 days.

The study population were adult subjects with chronic venous insufficiency. The number of subjects included into the study consisted of 30 persons, gender distribution was characterized by a predominance of females (66,6%). Mean age was 45,97 years, ranging between 32 years and 65 years. Mean weight was 72,8 kg, ranging between 42 kg and 120 kg, mean height was 169,5 with ranging between 150 cm and 182 cm. Each site enrolled 15 subjects.

The overall duration of the study was 2 months. Within this period the following variables were assessed: Aberdeen Varicose Veins Questionnaire (AVVQ), CIVIQ-2 Venous Quality of Life Questionnaire, Ultrasonography picture, QoL by Subject's questionnaire.

Study results

After 30 days of using SANKOM® Functional Patent Socks the mean reduction in Aberdeen Varicose Veins Questionnaire comprised 3,14 points. A number of subjects who have a positive response (reduction in scores) are 21 and 9 who had no response (increase in scores). The mean reduction in Aberdeen Varicose

Veins Questionnaire were 6,78 points for a subject with a positive response (reduction in scores). Study data showed a significant improvement in the quality of life based on the Aberdeen Varicose Veins Questionnaire.

Within 30 days of using SANKOM[®] Functional Patent Socks mean increasing Global Index Score of CIVIQ-20 comprised 22,7 points. A number of subjects who had a positive response (increase in scores) were 26 and 4 who had no response (reduce scores). Study data presented a significant improvement in the quality of life based on the assessment by Global Index Score of CIVIQ-20.

The study data indicated a significant reduction in the lumen of the veins in subjects at Visit 3 compared to the results at Visit 1 (- 0,93 mm).

Based on the integral results of ultrasound examination of the lower extremities, there was improvement noted with 27 subjects (90%). With 15 subjects (50%) it was reported as significant.

Analysis of patient's QoL self assessment showed high level of satisfaction and positive evaluation of all parameters evaluated in majority of study subjects.

Subjects included in the study were closely followed in each site and any adverse events were not reported by subjects or investigators.

Conclusions

Among the subjects with chronic venous disease (C1 – C2), those who used SANKOM[®] Functional Patent Socks were reported that 30 days of SANKOM[®] Functional Patent Socks use lead to a reduction in Aberdeen Varicose Veins Questionnaire by 3,14 points and mean increase of Global Index Score of CIVIQ-20 on 22,7 points. Additionally, the results of ultrasonography examination of the lower extremities showed improvement in 90% of subjects. This data confirms the hypothesis that SANKOM[®] Functional Patent Socks increase the quality of life. The application of SANKOM[®] Functional Patent Socks assessed as safe as no adverse events were reported during study.