A double-blind, randomized controlled trial of ciplukan (physalis angulata linn) extract on skin fibrosis, inflammatory, immunology, and fibrosis biomarkers in scleroderma patients

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Abstrak

scleroderma is an autoimmune disease characterized by organ fibrosis, resistant to standard treatment. It is suspected the addition of Physalis angulata Linn. (Ciplukan) extract as adjuvant therapy can improve the scleroderma skin fibrosis. The aim at this study is to evaluate the effect of ciplukan extract as adjuvant on scleroderma skin fibrosis in standard therapy, based on modified Rodnan skin scale (MRSS), inflammatory biomarkers, immunology and serum fibrosis.
Methods: double-blind, randomized clinical trial was performed in scleroderma patients with stable disease at Cipto Mangunkusumo hospital and Hasan Sadikin hospital during November 2015March 2017 who met the selection criteria and continued to receive standard therapy. The subjects were randomly allocated into two groups: the study group received the ciplukan extract 3 x 250 mg / day for 12 weeks and the placebo group. Examination of MRSS, ESR, P1NP, BAFF and sCD40L was performed every 4 weeks until the end of the study.
Results: fifty-nine subjects completed the study. They consisted of 29 subjects of the treatment group and 30 of the placebo group, with an average age of 41 (SD 9) years, the proportion of women: male = 9 : 1. There was a significant improvement of skin fibrosis in the study group with a highly significant decrease in MRSS (35.9% VS 6.3%, p <0.001) and a relative decrease in P1NP levels (17.8% VS 0.7%, p = 0.002). No decrease in ESR, BAFF and sCD40L levels in both groups. There was a weak but significant positive correlation between MRSS with P1NP levels (r = 0.236, p = 0.036). Conclusion: Ciplukan extract with dose 3 x 250 mg for 12 weeks as adjuvant on scleroderma standard therapy alleviates skin fibrosis significantly based on MRSS and P1NP levels.
.....Latar belakang: skleroderma merupakan penyakit autoimun yang resisten terhadap pengobatan standar, penambahan ekstrak herba ciplukan (Physalis angulata Linn) diduga dapat memperbaiki fibrosis kulit skleroderma. Penelitian ini bertujuan mengkaji peran ekstrak herba Ciplukan sebagai terapi ajuvan untuk fibrosis kulit skleroderma yang mendapat terapi standar, berdasarkan MRSS, biomarker inflamasi, imunologi dan fibrosis serum.
Metode: uji klinis acak tersamar ganda pada pasien skleroderma stabil yang berobat jalan di RSCM dan RSHS sejak November 2015Maret 2017 yang memenuhi kriteria inklusi dan menerima terapi standar. Subjek secara random terbagi dua: kelompok uji yang mendapat ekstrak herba C iplukan 3x 250 mg/hari selama 12 minggu dan kelompok plasebo. Pemeriksaan MRSS, LED, P1NP, BAFF dan sCD40L dilakukan setiap 4 minggu hingga akhir penelitian.
Hasil: lima puluh sembilan subjek menyelesaikan penelitian, 29 subjek kelompok uji dan 30 subjek kelompok plasebo, rerata usia 41 (SB 9) tahun, proporsi wanita : pria = 9 : 1. Ditemukan perbaikan fibrosis kulit bermakna pada kelompok uji dengan penurunan relatif MRSS sebesar 35,9% dibandingkan plasebo 6,3% dengan p < 0,001 dan penurunan relatif bermakna kadar P1NP sebesar 17,8% dibandingkan plasebo 0,7% dengan p = 0,002. Tidak ditemukan penurunan kadar LED, BAFF dan sCD40L pada kedua kelompok.

Terdapat korelasi positif bermakna antara MRSS dengan kadar P1NP (r = 0,236, p = 0,036).
Kesimpulan: pemberian ekstrak etanol herba ciplukan dosis 3 x 250 mg selama 12 minggu sebagai terapi ajuvan pada skleroderma dalam terapi standar, secara klinis dan statistik menunjukkan perbaikan kelainan fibrosis kulit berdasarkan MRSS dan biomarker fibrosis P1NP serum secara bermakna dibandingkan kontrol.