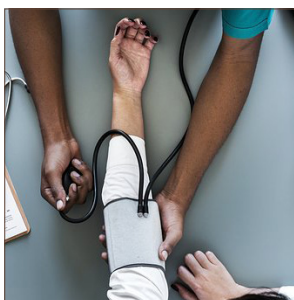


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Palliative Care 2019 *Clinical Trials 2019*



Joint Event on
2nd International Conference on
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Clinical Trials and Pharmacovigilance
September 23-24, 2019 | Prague, Czech Republic

Palliative Care & Clinical Trials and Pharmacovigilance

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Efficacy of N-SORB® a proprietary KD120 MEC metabolically activated enzyme formulation: A randomized, double-blind, placebo-controlled study

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Background: Enzymes are crucial for all aspects of metabolic function. Digestive enzymes from natural sources have been credited with beneficial effects in the digestion and absorption of food. N-SORB is a novel KD120 multienzyme complex (MEC) of metabolically activated enzymes composed of proteases, amylases, lipases, alpha-galactosidase, and glucoamylase from natural sources. These enzymes are encapsulated in a SK713 SLP (non-GMO soy lecithin phospholipid) absorption technology (Prodosome®).

Objective: This randomized, double-blind placebo-controlled investigation assessed the safety and efficacy of N-Sorb in healthy male and female volunteers on blood parameters, immunity, body composition, physical health, and quality of life (QOL).

Methods: Forty-six male and female (mean age: 25.8 - 12.1 years) healthy volunteers, were randomly assigned to receive either N-SORB (1 mL, twice daily) or placebo for 90 consecutive days. Complete blood count, as well as blood glucose, liver enzymes, and lipid profile were assessed pre- and post-intervention. Serum cytokine levels were determined by using a Bio-Plex Pro Human Cytokine 8-plex assay. Whole body composition analysis was performed by dual-energy X-Ray absorptivity (DEXA) to determine body fat mass, lean mass and android and gynoid fat. Body weight, blood pressure, and physical health were assessed. Changes in quality of life

was examined using the World Health Organization QOL-abbreviated version (WHOQOL-BREF) and sleep quality was assessed using the 24-item Pittsburgh Sleep Quality Index (PSQI) questionnaire. Adverse events were monitored.

Results: A total of 40 subjects successfully completed the study. Compared to placebo, changes in blood cell counts including haematocrit, haemoglobin, mean corpuscular volume, platelets and lymphocytes provide evidence of some improvement. QOL parameters showed a small but significant improvement in the N-SORB group. A significant increase was observed in AST level in the placebo group at the end of 90 days of treatment, however, no increase was observed in the N-SORB group. No significant changes in BUN, serum creatinine, ALP, ALT, and lipid profile were observed.

Conclusion: This study demonstrates that short-term intervention with N-SORB improves the QOL and PSQI in healthy volunteers and marginally improved cardiometabolic parameters, lipid profile or body composition. No adverse effects were reported.

Speaker Biography

Manashi Bagchi is the professor in the University of Houston College of Pharmacy at USA. Her research interest is clinical pharmacy.

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Inactivity behavior and exercise barriers in patients with Behçet disease

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Introduction: Behçet's Disease (BD) is a chronic, inflammatory, rheumatic disease that is characterized by mucocutaneous lesions and can be seen major organ involvement such as eyes, musculoskeletal system, gastrointestinal system and central nervous system. Impaired quality of life, aerobic capacity, respiratory function and life satisfaction, sleep disorders, depression, anxiety and fatigue are seen commonly in BD patients like the other rheumatic diseases. Considering that regular physical activity effects survival for patients and healthy people, it is important to determine the factors affecting physical activity level and exercise barriers. The aim of this study is to investigate physical activity level and exercise barriers in patients with BD.

Methods: Twenty-eight patients were included in the study. Physical activity level, exercise barriers, fatigue, depression, pain, quality of life and aerobic capacity were evaluated with International Physical Activity Questionnaire (IPAQ), Exercise Barriers and Benefits Scale (EBBS), Fatigue Severity Scale (FSS), Beck Depression Inventory (BDI), Visual Analog Scale (VAS),

Behçet's Disease Quality of Life Questionnaire (BDQoL) and 6 minutes walk test, respectively.

Results: According to our results, 46.4% of patients were physically inactive and 42.8% of patients were moderate active. There was a significantly correlation between physical activity score and exercise barriers ($p < 0.05$).

Conclusion: As with other rheumatic diseases, for SLE patients' rehabilitation, exercise is of great importance because of its positive contribution to the musculoskeletal system. Thinking of negative affects of physical inactivity, patients with Behçet disease should be encouraged to exercise. Also, reasons of physical inactivity should be investigated and treated.

Speaker Biography

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Relationship between thoracic kyphosis and shoulder muscle strength and shoulder joint motion in male patients with ankylosing spondylitis

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Introduction: Ankylosing Spondylitis (AS) is a rheumatologic disease that primarily affects the axial skeleton. Spinal inflammation, increased ossification of the ligaments and syndesmophytes in the spinal column can cause an increase in thoracic kyphosis in the AS patients. Negative effects of thoracic kyphosis on shoulder functions have been reported in studies performed in different populations. The aim of our study is to determine the relationship between thoracic kyphosis and shoulder functions in male patients with AS.

Methods: Twenty-three (23) male participants (age: 41.18±11.89 year, body mass index: 26.25±5.02kg/m²) diagnosed with AS according to the Modified New York criteria were included the study. Thoracic kyphosis angle and shoulder motion were evaluated with digital inclinometer. Strength of shoulder muscles were evaluated with digital hand-held dynamometer. Pearson correlation test and Spearman correlation test were used for statistical analysis.

Results: Thoracic kyphosis angle showed negative correlations with dominant side shoulder flexion active range of motion (AROM) (p<0.001; rho:-0.711), abduction AROM (p:0.007; rho:-0.545), external rotation AROM (p:0.008;rho:-0.536) and non-


dominant side shoulder flexion AROM (p<0.001;rho:-0.768), abduction AROM (p:0.008;rho:-0.540), external rotation AROM (p:0.005;rho:-0.563). There was no correlation between thoracic kyphosis angle and shoulder abduction and flexion muscle strength.

Discussion: As a result of our study, it was determined that in patients with male AS, thoracic kyphosis angle was correlated with shoulder flexion AROM, abduction AROM and external rotation AROM. There are muscular and mechanical connections between the spinal column, scapula, clavicle and humerus. The position changes of these bone structures biomechanically affect each other. We think that as the thoracic kyphosis angle increases, the shoulder mobility decreases in male patients with AS because of this reason. In light of this knowledge, therapeutic approaches to thoracic hyperkyphosis will benefit for the shoulder mobility in AS patients.

Speaker Biography

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Do hand functions effect in male patients with ankylosing spondylitis?

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Introduction and Aim: Proximal joints, especially hip and shoulder joint dysfunction, are seen in patients with Ankylosing Spondylitis (AS). While functional disorders for these joints are mentioned in the literature, studies on hand functions are limited. A limited number of studies have examined the grip strength in AS patients; but the results of these studies are also contradictory. According to our knowledge, there were no studies investigating hand dexterity in AS patients. The aim of this study was to investigate hand functions in male patients with AS.

Materials and Methods: A total of 48 participants were included in the study, 24 of whom were male patients (age: 40.08 ± 11.09 year, body mass index: 26.39±4.19kg/m²) diagnosed with AS according to the Modified New York criteria and 24 of whom were healthy adults (age: 40.04 ± 12.69 year, body mass index: 28.08 ± 3.74 kg/m²). The grip strength of the participants was assessed by a hydraulic hand dynamometer; the hand dexterity was assessed by a nine-hole peg test (9-HPT). Student's T Test and Mann-Whitney U Test were used for statistical analysis.

Results: Grip strength of male patients with AS decreased with respect to healthy male both on the dominant side (p: 0,002) and on the non-dominant side (p: 0,004). Also, hand dexterity was similar in both the dominant side (p: 0,151) and the non-dominant side (p: 0,564).

Discussion and Conclusion: As a result of the study, it was determined that while the grip strength was decrease in AS patients compared to healthy men, the hand dexterity did not change. While intrinsic muscle activity is more active in 9-HPT, extrinsic muscle activity is more active in grip strength. We think that the decrease in grip strength may be due to a decrease in especially upper extremity extrinsic muscle strength in patients with AS

Speaker Biography

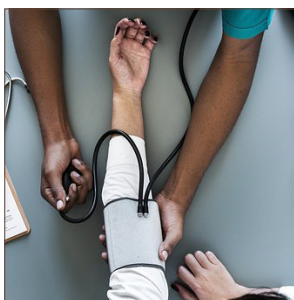
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Accepted Abstracts

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Alopurinol-induced TEN and association with HLA B*58:01 in white patients


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We have read the article 'A retrospective investigation of Human Leucocytic Antigen (HLA). B*5801 in hiperuricemia patients in a Han population of China' by Cheng et al. We would like to congratulate the authors for this succesful publication and make some contributions. We have had several cases in the intensive care section of our burn care unit involving White patients who developed Lyell's syndrome – all of them confirmed by biopsy – attributed to the use of allopurinol. Although the correlation between HLA B*58:01

and toxic epidermal necrolysis (TEN) has been described in Asian patients, we have begun to perform HLA genetic study in patients presenting with Lyell's síndrome associated with allopurinol, in order to avoid treatment with xanthine oxidase inhibitors in direct family of these, not only in Asian patients. Given this fact, it might be advisable to set up a HLA B*58:01 screening program in all patients with allopurinolinduced TEN, regardless of their race.

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Weekly cabazitaxel in elderly patients (EP) with metastatic castration resistant prostate cancer (mCRPC) progressing after docetaxel treatment: WeCabE, a phase II study

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Background: Cabazitaxel (Cab) every 3 weeks with daily prednisone is considered a possible option as second line chemotherapy in mCRPC. According to SIOG guidelines the G8 Screening Tool might be useful to detect unfit EP.

Methods: EP with mCRPC, ≥ 70 and < 85 years, G8 Score 8-14 which identify unfit patients (i.e. no frail, no fit), PS 0-2 were enrolled.

Cab was administered at a dose of $8\text{mg}/\text{m}^2$ for 4 out 5 weeks. Primary end point was PFS. Secondary endpoints were: PSA Response, ORR, OS, Safety, impact on Geriatric assessment according with Elderly Task Force EORTC.

Results: At time of this analysis 14 EP were analysed. Median age was 78 years, 35.7% of pts were 80-85 years. Median number of cycles received, in pts who ended treatment was

4. Overall 55.6% of pts reached a PSA response while 33.3% achieved a stability. 42.8% of pts ended therapy without a worsening/rising of symptoms.

G8 best score improvement during treatment was 1.28 (median). The most common AE G 3-4 was fatigue (20%) while G1-2 toxicities were diarrhea (40%) and fatigue (60%). Only one pt experienced neutropenia and anemia G3-4.

Conclusions: These preliminary results confirm the usefulness of G8 tool to identify elderly mCRPC pts suitable to receive chemotherapy. It suggests that weekly cab in mCRPC EP (including very old pts > 80), is effective, with a manageable safety profile.

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Understanding of clinical investigator about the serious adverse event reporting and its complexity in Latin America

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In Latin America, different efforts are being made to increase clinical studies, working on the speed of evaluation and approval of these. Likewise the need for new drugs and medical devices and its offer to improvements in healthcare. Clinical research is undertaken to elucidate product benefits, but also to identify potential harms. The report of Adverse event (AE) and serious AE (SAE) bring crucial information in drug and device development.

Unfortunately, there is an increasing of requirements from health authority that trigger in requirements by the sponsors to the research centers, leading to a decrease in the uptake of have a robust training and capacity building program which is

strengthening the focus on patient. Therefore, it is essential that both researchers and coordinators genuinely understand the impact of the information contained in the reports and the value of quality in their evaluation.

The value proposal launched with this initiative is aimed that academics from different universities work virtually with the industry, in order to strengthen research centers selection during the feasibility process, also, do a reengineering on training of the research team focus on the observation of patient beyond of physical or laboratory tests.

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