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Abstract Book

Conclusion: In this work we have established and characterized a primary cell line of human bone marrow mesenchymal stem cells to study the cellular and molecular alterations at the base of the GSD disease. The establishment of this in vitro model will permit identifying which could be the molecular and epigenetics mechanisms responsible for the altered mineralization process and the inhibition of bone regeneration in osteolytic lesions of GSD. This study will permit not only to understand the molecular basis of the altered bone homeostasis in GSD, but also to understand if molecules as miRNAs are involved in this process and if they could be molecular target to development of new therapeutic strategies against GSD.

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ASSOCIATION BETWEEN CLINICAL FEATURES AND IL-6, IL-10 LEVELS IN HOSPITALIZED PATIENTS INFECTED WITH COVID-19

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Objective: Upper respiratory tract infection symptoms, worsening cough, fever, anosmia, respiratory failure, various complications and even death may be detected in COVID-19 infection (1-3). The aim of this study was to determine association between clinical features and IL-6, IL-10 levels in hospitalized patients infected with COVID-19.

Methods: A cross-sectional study was conducted of patients at Baskent University between March 11 and December 31, 2020. Hospitalized patients aged above 18 y, diagnosed with COVID-19 via RT-PCR from nasopharyngeal or throat swab specimens are included the study. Pregnant patients, those with severe endstage disease or with missing documentation were excluded. Data were obtained from electronic health records. Information was collected about patient demographics; comorbidities; history and duration of complaints, history of fever or anosmia, respiratory problems, length of stay, history of intensive care, biochemical parameters and IL-6, IL-10 levels. The correlation between clinical features and IL-6, IL-10 levels were observed. P-value <0.05 was considered statistically significant.

Results: Total 109 patients included to the study. 39.45% of patients were female (n=66), 60.55% of patients were male (n=43). Mean duration of hospitalization was 7.54 ± 6.53 d, intensive care duration was 2.19 ± 6.28 d and O₂ support duration was 6.97 ± 6.60 d. Mean IL-6 level was 40.23 ± 123.78 and IL-10 level was 36.47 ± 66.21 . Mean basal C-reactive protein (CRP) was 56.30 ± 56.62 mg/L and control CRP was 60.82 ± 150.93 mg/L. There was significant correlation between CRP, fever, length of stay, duration of intensive care, control CRP and IL-6 levels ($p < 0.05$). There was significant correlation between IL-6 level, control CRP, length of stay, duration of intensive care, oxygen

support ($p < 0.05$). There was significant correlation between arthralgia and IL-6 levels ($p = 0.037$) but there was no correlation fever and anosmia ($p > 0.05$). Correlation between IL-10 levels and duration of intensive care was significant ($p < 0.05$). Also correlation between control CRP and length of stay, duration of intensive care, oxygen support was detected ($p < 0.05$).

Conclusion: There may be correlation between clinical features like length of stay, duration of intensive care, oxygen support, CRP and interleukin levels in hospitalized COVID-19 infected patients.

References:

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IMPACT OF REHABILITATION TECHNOLOGIES ON QUALITY OF LIFE INDICATORS IN PATIENTS WITH RHEUMATOID ARTHRITIS AND OSTEOARTHRITIS WITH COMORBID PATHOLOGY

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Objective: To evaluate the effectiveness of a post-hospital rehabilitation program (PHRP) on the dynamics of health-related quality of life (HRQoL) indicators in patients with rheumatic diseases (RD) combined with arterial hypertension (AH).

Methods: We examined 66 patients with osteoarthritis (OA) (mean age $56.8 [46.4:73.8]$ years old, disease duration $12.8 [6.5:24.3]$ y) and 94 patients with rheumatoid arthritis (RA) (mean age 52.1 ± 9.6 years old, disease duration $9.2 [4.8:13.6]$ y) with signs of AH. HRQoL was studied using the Short Form 36-item Health Status Questionnaire (SF-36). PHRP (kinesotherapy, low-frequency magnetic therapy - LFMT and biofeedback therapy) was used in the complex treatment of RA (group I, n=53) and OA patients (group III, n=30). Other patients with RA (group II, n=41) and OA (group IV, n=33) did not receive PHRP.

Results: A combined mean HRQoL score for the physical and mental components of the SF-36 was preliminarily calculated in patients. RA patients showed significant impairments in the physical sphere ($p=0.006$); OA patients showed impairments in the mental sphere ($p=0.033$). We found that a more severe increase in blood pressure in RA patients was more strongly associated with the patients' physical health scores (PF: $r=-0.38$, $p=0.019$ and BP: $r=-0.33$, $p=0.041$) than with the other SF-36 subscales. After

PHRP (3-week course), group I showed improvement on six SF-36 scales (PF, RP, VT, SF, RE, MH), group III showed improvement on five SF-36 scales (MH, SF, GH, VT, RE), and groups II and IV showed improvement on three and two scales (PF, SF, MH and RE, BP). Group I showed the highest increase in physical function scores (PF, p=0.011; RP, p=0.045), general health (GH, p=0.036), vitality (VT, p=0.02), social functioning (SF, p=0.046), and mental health (MH, p=0.039), while group III showed the highest increases in social functioning (SF, p=0.028), mental health (MH, p=0.031), and general health (GH, p=0.022). These results can be explained by the combined effect of PHRP on both the physical (kinesotherapy and LFMT) and mental (biofeedback therapy) components of HRQoL.

Conclusion: Patients with RD and AH have lower quality of life indicators. Periodic assessment of HRQoL dynamics and wide use of nonmedicamental methods of treatment for health improvement are recommended in this group of patients.

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TWO EXPERIMENTAL RAT MODELS FOR STUDYING DEGENERATIVE CHANGES IN THE LUMBAR PARAVERTEBRAL MUSCLES

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Objective: To study the structural features of the lumbar m. multifidus and the m. psoas after keeping rats on a high-fat diet (obesity) or compressing their lumbar paraspinal muscles by binding its using Nurolon® 3.

Methods: The study was performed on 2-month-old male rats (n=15) into three groups. Control animals (n=5) were fed standard chow without any surgery. Model I: rats (n=5) were kept on a high-fat diet (40-45% kcal from fat) without any surgery also. Model II: rats (n=5) underwent a paraspinal muscles compression. The paraspinal muscles were tied from L2 to S1 with Nurolon 3 until the tied muscle became pale at each vertebral level to induce muscle ischemia. The experiment lasted for 90 days, after those fragments of the lumbar m. multifidus and m. psoas removed and histomorphometry analysis performed. The percentage of fat for Model I and fibrous tissue for Model II relative to the total area of said muscles was calculated.

Results: In the control group, m. multifidus and m. psoas maintained normal structure. It was determined that the fat area in the m. multifidus was 4.1 times larger than the fat area in the m. psoas (p<0.001). 12 weeks from the beginning of the experiment, the high-fat diet rats (model I) weighed, on average, 22% (p=0.001) more than the control group rats. Similar degenerative changes such as uneven muscle fibre width and sarcoplasm colouring, 'wavy' and swollen fibres, loss of striation, karyopyknosis were

observed in the lumbar paraspinal muscles in both models. The structural changes found in model I are classified as fat dystrophy. As opposed to the control group and the model I, in the perimysium and endomysium of rats from the model II, large areas of fibrous tissues with high fibroblast density were discovered. The fat area in the m. psoas was greater in model I than in the control by 2.2 times (p<0.001), but 3.3 times less than in the m. multifidus of the same animals (p<0.001). In model I the fat area in the m. multifidus was 1.8 times larger (p<0.001) and in the m. psoas was greater by 2.2 times (p<0.001) than in the control. Fibrous tissue replaced muscle fibres in m. multifidus in model II and was 12.66%.

Conclusion: The relevance of the models is proven: after 3 months, it is possible to obtain degenerative changes in the muscle tissue that are extremely similar to those observed in the muscles of patients with degenerative spine diseases.

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PHASE I/III STUDY TO CONFIRM BIOEQUIVALENCE AND SAFETY OF PROPOSED BIOSIMILAR (MB09) EU-DENOSUMAB IN POSTMENOPAUSAL WOMEN WITH OSTEOPOROSIS

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Objective: To conduct a phase I/III study to compare the efficacy, pharmacokinetics, pharmacodynamics, safety and immunogenicity of MB09 (proposed Denosumab biosimilar, BsD) vs. European Union-Reference Denosumab (EU-RD) in postmenopausal women with osteoporosis (PMO).

Methods: PMO was chosen as a sensitive indication to confirm bioequivalence of BsD with its reference. SIMBA Study is a multicentre, multinational global comparative efficacy study (MB09-C-01-19), randomised, double-blind, parallel 3 arm study. 528 eligible PMO patients 55-80 y of age with an absolute lumbar spine BMD (LS-BMD) T-score between ≤ -2.5 and ≥ -4 during screening period will be randomised in a 2:1:1 ratio to receive BsD - BsD (Arm 1), EU-RD - BsD (Arm 2), or EU-RD - EU-RD (Arm 3). In main treatment period, patients will receive BsD or EU-RD (60 mg subcutaneous at day 1 and month 6). In transition/safety Follow-up period (month 12 to month 18), patients receive third dose at month 12. The women in arm 2 receiving EU-RD, will be switched to the biosimilar (MB09). All other patients continue their treatment up to month 12. (Figure)