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THU0157

REASONS FOR NON-PARTICIPATION IN A RANDOMIZED CONTROLLED TRIAL COMPARING TWO SEASONAL INFLUENZA VACCINES IN RHEUMATOID ARTHRITIS PATIENTS

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Background: Low recruitment rates (12%) into influenza vaccine studies are reported among healthy older adults. Fear of side effects, lack of insight into personal risk status, and doubts about vaccine efficacy are the most commonly reported reasons for non-participation¹. Rheumatoid arthritis (RA) patients are also at high risk for influenza and benefit from yearly immunization². A number of influenza vaccines are currently available; however, it is unknown which vaccine(s) provides optimal protection to RA patients. Estimating participation rates is key for designing studies to address that issue.

Objectives: To define the rate of non-participation and reported reasons for refusing entry into a randomized clinical trial (RCT) comparing two influenza vaccine formulations (NCT02936180 - ClinicalTrials.gov).

Methods: Seropositive RA patients from McGill University Health Centre, on stable treatment prior to recruitment (≥ 3 months), were invited by their treating rheumatologists to participate in the study. A vaccine nurse contacted participants from Year 1 (Y1) and those from Year 2 (Y2) encountered a recruiter immediately after their rheumatologist's appointment. Patients who agreed to participate signed the consent form and were later contacted by a vaccine nurse to schedule their appointment. Reasons for non-participation were documented.

Results: Over two influenza seasons, 692 RA patients were invited to participate in the study. The non-participation rate was 59.5% (Y1=64.6%, Y2= 53.1%, $p=0.1$). Non-participants and participants did not differ in age or sex (age mean $\pm$ SD: 61.7 $\pm$ 14.7 vs 60.9 $\pm$ 12.9, $p=0.5$; female sex%: 76.8 vs 79.9, $p=0.33$). Inclusion and exclusion criteria resulted in the loss of 17 (4.1%) and 19 (4.6%) subjects, respectively. The three most commonly reported reasons for non-participation were vaccine misconceptions ($n=49$, 20.4%), reluctance to participate in a clinical trial ($n=35$, 14.6%), and lack of available time ($n=29$, 12.1%). Thirty-one patients reported more than one reason for non-participation. Reasons for non-participation were similar according to sex and patient age ($>$ or $<$ 65 years).

Conclusion: Only half of eligible RA patients accepted to be enrolled in this influenza vaccine study. Enhancing patient literacy on vaccines and the relevance of conducting clinical trials is essential to optimize both recruitment to such trials and immunization rates.

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THU0158

IMPAIRED OLFACTORY FUNCTION IN PATIENTS WITH RHEUMATOID ARTHRITIS

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Background: Recent studies indicated that rheumatic disorder can be associated with olfactory loss.

Objectives: To specifically investigate chemosensory function in patients with rheumatoid arthritis (RA) by valid and reliable psychophysical tests and compare them to healthy controls.

Methods: We investigated 212 RA patients (43 men, 169 women; mean age 59 years) and compared their results to 30 healthy controls (10 men, 20 women; mean age 40 years). All participants received standardized olfactory (odor thresholds, odor discrimination and identification for suprathreshold testing) and gustatory tests (taste sprays – suprathreshold taste function; taste strips – quasi-threshold gustatory test). In addition, blood chemistry was also assessed (e.g., for CRP, RA factors, and anti-CCP).

Results: RA patients rated their senses of smell and taste to be as good as that of controls. However, in RA patients 4% were found to be anosmic, and 36% to be hyposmic. These numbers were 0 and 20%, respectively, in controls. RA patients exhibited significantly lower scores in odor identification and discrimination. Gustatory test scores were also decreased in RA patients. No such differences were found for odor thresholds. Interestingly, the changes in olfactory and gustatory function neither correlated with disease duration nor with indicators of RA activity or severity like C-reactive protein, rheumatoid factors, anti-CCP antibodies or DAS28-Score. Moreover, there was no correlation between olfactory dysfunction and treatment with DMARDs, e.g. amount of MTX, or Tumor necrosis factor α inhibitors.

Conclusion: These results indicate that olfactory and gustatory function is significantly decreased in patients with RA. This decrease in function seems to be unnoticed by most patients which may be due to the fact that RA patients have no complete loss of function (anosmia), but still function in the range of hyposmia or even normosmia. Importantly, the changes in olfactory function are not observed at the level of odor thresholds but only for suprathreshold tasks, which may suggest that the decrease in function is due to higher-order central-nervous processing of olfactory information. In addition, the lack of correlations between disease parameters and chemosensory dysfunction indicates that the decrease in chemosensory function may be a trait characteristic of RA patients.

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THU0159

RISK FACTORS FOR DEVELOPING SARCOPENIA IN PATIENTS WITH RHEUMATOID ARTHRITIS AT 2 YEARS: FROM THE CHIKARA STUDY

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Background: Patients with rheumatoid arthritis (RA) are at higher risk of sarcopenia due to joint dysfunction and chronic inflammation. The prospective observational CHIKARA study (Correlation research of sarcopenia, skeletal muscle and disease activity in rheumatoid arthritis; registration number UMIN000023744) was started in 2016 to clarify the correlation between RA disease activity and sarcopenia. We reported that glucocorticoid use and low body fat were independent risk factors for developing sarcopenia at 1 year in RA patients last year.

Objectives: Risk factors for sarcopenia were investigated over a 2-year period this time.

Methods: 100 patients (78 female, average age 68 years) enrolled in the prospective CHIKARA study underwent examinations of body composition (body weight, muscle mass, fat mass, predicted bone mass, etc.; measured by a body composition analyzer (MC-780A; TANITA, Tokyo, Japan)), laboratory data, disease activity, Health Assessment Questionnaire (HAQ), and treatment condition at baseline and at 2 years. Sarcopenia was diagnosed using the criteria of the Asia Working Group on Sarcopenia. Of 64 patients without sarcopenia at baseline, those who developed sarcopenia at 2 years were identified, and risk factors were investigated by univariate and multivariate analyses.

Results: Six patients (9.4%) developed sarcopenia during the 2-year follow-up. Glucocorticoid use >5 mg/day was significantly higher ($p=0.009$), and MMP3 ($p=0.018$) and HAQ ($p=0.045$) were significantly increased in the patients who developed sarcopenia during the 2-year follow-up. Sarcopenia development was significantly associated with male sex ($r=0.28$, $p=0.03$), age ($r=0.27$, $p=0.03$), glucocorticoid use >5 mg/day ($r=0.33$,