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OP0069

PERFORMANCE OF AMERICAN COLLEGE OF RHEUMATOLOGY (ACR) COMBINED RESPONSE INDEX IN DIFFUSE CUTANEOUS SYSTEMIC SCLEROSIS (CRISS) SCORE IN PHASE 2 TRIAL OF LENABASUM IN DIFFUSE CUTANEOUS SYSTEMIC SCLEROSIS (DCSS)

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Background: Change in modified Rodnan skin score (mRSS) has been used as primary efficacy outcome in at least 13 failed controlled studies in dcSSc. In 2016, the CRISS score was provisionally accepted by ACR as a primary efficacy outcome for clinical trials in dcSSc. Its performance as a primary efficacy outcome has not been tested in a clinical trial.

Objectives: To evaluate performance of ACR CRISS outcome measure in the lenabasum Phase 2 study in dcSSc, the first study in which it was used prospectively as the primary efficacy outcome.

Methods: The Phase 2 study JBT101-SSc-001 (NCT02465437) included a 16-week, double-blinded, randomized, placebo-controlled Part A followed by an open-label extension (OLE). ACR CRISS score is calculated from a weighted exponential formula that includes change in mRSS, Patient Global Assessment (PtGA), HAQ-DI, Physician Global Assessment (MDGA), and FVC% predicted. Spearman correlations were determined for: pairs of core items at Baseline; change in pairs of core items; and change in a given core item and calculated ACR CRISS score. Median ACR CRISS scores were determined in subjects with different levels of improvement in patient-reported outcomes (PROs).

Results: Correlations among pairs of CRISS core items at baseline and change in core items were all < 0.80 at 4 and 12 months. The strongest correlations ($r \geq 0.60$, $P \leq 0.0001$) for core items at baseline were between PtGA and HAQ-DI, HAQ-DI and MDGA, and PtGA and MDGA. The strongest correlations ($r \geq 0.50$, $P \leq 0.001$) for changes in pairs of core items were between PtGA and HAQ-DI, HAQ-DI and MDGA, and MDGA and mRSS, all others were ≤ 0.30 (Table 1). Correlations between change in each core item and ACR CRISS score were all statistically significant, $p \leq 0.05$ at both 4 and 12 months and very strong for change in mRSS and ACR CRISS (Table 1).

Median ACR CRISS scores increased with increasing levels of improvement in PROs that were core items (HAQ-DI and PtGA) and even PROs (PROMIS-29 domains) that were not core items. Median ACR CRISS score associated with improvement in HAQ-DI at least -0.250 points was 0.82 and associated with at least 1-point improvement in PtGA was 0.53 at 12 months.

Table 1. Correlation of ACR CRISS with Change in Core Item, r

Time	Correlation of ACR CRISS with Change in Core Item, r				
	mRSS	PtGA	HAQ-DI	MDGA	FVC% predicted
4 months	-0.91	-0.37	-0.45	-0.66	0.38
12 months	-0.76	-0.38	-0.39	-0.38	0.54

Conclusion: In the context of the lenabasum Phase 2 clinical trial, ACR CRISS core items at baseline and change in ACR core items were not redundant ($r < 0.80$). Change in each core item correlated with ACR CRISS score, indicating each contributed to the score at both 4 and 12 months. The 12-month median ACR CRISS score was higher in subjects with greater levels of improvement in PROs, even PRO that were not core items, showing that ACR CRISS score reflects long-term clinical benefit in how the patient feels and functions. These data provide preliminary evaluation of the ACR CRISS score as a clinical trial endpoint in dcSSc.

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Bringing digital health care solutions to patients

OP0070-PARE

GEOCACHING AS AN ENCOURAGEMENT FOR BEING ACTIVE

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Background: The Finnish Rheumatism Association and Novartis started a project in 2017 to energise our local associations, members and their families by adapting an active lifestyle. Geocaching is a fun, family-friendly way to exercise both mind and body. It is for everybody to enjoy.

Geocaching is an outdoor recreational activity, in which participants use a Global Positioning System (GPS) receiver or mobile device and other navigational techniques to hide and seek containers, called "geocaches" or "caches", at specific locations marked by coordinates all over the world.

There are about three million geocaches hidden around the world. A typical cache is a small waterproof container containing a logbook and sometimes a pen or pencil. The geocacher signs the log with their established code name and dates it to prove that they found the cache. After signing the log, the cache must be placed back exactly where it was found.

Objectives: The main goal of the project was to hide 70 new caches all over Finland to create an enjoyable experience for other geocachers. Those caches were named "Reumageo" at the beginning of the cachename. For all the associations that were involved in this project received money allocated to sport and physical activity out of the 15,000 euro project budget. The project ended on 12 October 2018, and all logged caches were included in the game.

Methods: We started our project by training association representatives. The training included the basics of geocaching: how to find caches, how to hide your cache and create your cache page, different geocachetypes and everything you should know geocaching. The trained representatives told about geocaching in their own associations, and they were responsible for creating at least 2-3 new caches and handling the new caches. The main idea was that when you have found about 15-20 caches you would start to hide your own caches. Together with local associations our aim was to create 70 caches all over Finland to celebrate the 70-year-old Finnish Rheumatism Association.

Outdoor geocaching adventure starts indoors with preparation and online research. You need a Global Positioning System (GPS) receiver or a mobile device, your own account at the site geocaching.com. The site offers a completely free access to the caching data and all the site features. The site offers also a "premium" member status to access certain features. You can also download the Geocaching intro app onto your smartphone, like Geocaching.