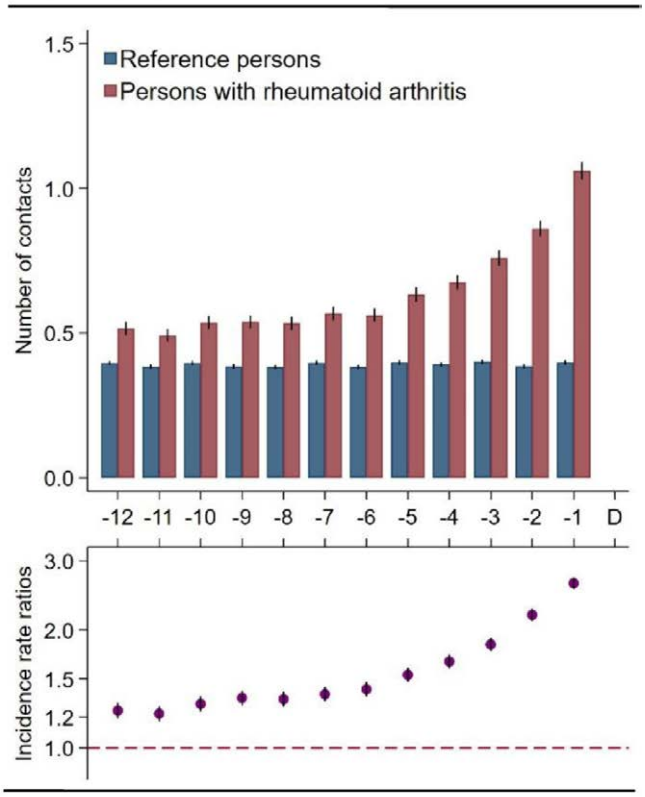
is diagnosed, and it indicates that a window of opportunity exists to expedite referral to specialist care and the diagnosis of RA.

Figure 1: Contacts with a general practitioner in the 12 months preceding the date of a rheumatoid arthritis diagnosis and a corresponding index date assigned to references persons without rheumatoid arthritis.



Upper part: unadjusted rates. Lower part: incidence rate rations adjusted for age, civil status, ethnicity, educational level, household income and comorbidity.
Black lines represent 95% confidence intervals.

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OP0038

VITAMIN D AND MARINE N-3 FATTY ACID SUPPLEMENTATION FOR PREVENTION OF AUTOIMMUNE DISEASE IN THE VITAL RANDOMIZED CONTROLLED TRIAL: OUTCOMES OVER 7 YEARS

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Background: Strong biologic rationale supports both vitamin D and marine omega-3 (n-3) fatty acids for prevention of autoimmune disease (AD). Within the randomized, double-blind, placebo-controlled **VIT**amin D and Omeg**A**-3 Tria**L** (**VITAL**), we tested the effects of these supplements on AD incidence. We previously reported results after 5.3 years of randomized follow-up showing overall protective effects for vitamin D on AD incidence (HR 0.78, 95% CI 0.61-0.99) and suggestive results for n-3 fatty acids (HR 0.85, 95%CI 0.67-1.08)[1].
Objectives: We aimed to test effects of these supplements with two more years of post-intervention follow-up in VITAL.
Methods: VITAL enrolled and randomized men and women (age ≥50 and ≥55 years, respectively) in a 2-by-2 factorial design to vitamin D_3 (2000 IU/d) and/or n-3 fatty acids (1000 mg/d) or placebo and followed for median 5.3 years. Here, we followed participants for another 2 years of observation to assess for sustained effects. Incident AD diagnoses were reported by participants annually and confirmed by medical record review by expert physicians using existing classification criteria. The primary endpoint was total incident AD, including rheumatoid arthritis (RA), polymyalgia rheumatica (PMR), autoimmune thyroid disease (AITD), psoriasis, and all others. Pre-specified secondary endpoints included individual common AD; and probable AD. Cox models calcuated hazard ratios (HR) for incident ADs.
Results: Of 25,871 participants randomized, 71% self-reported non-Hispanic Whites, 20% Black, 9% other racial/ethnic groups, 51% women, mean age was 67.1 years. During 7.5 years median follow-up, confirmed AD was diagnosed in 156 participants in vitamin D arm vs 198 in vitamin D placebo arm, HR 0.79 (0.64-0.97). Incident AD was confirmed in 167 participants in n-3 fatty acid arm and 187 in n-3 fatty acid placebo arm, HR 0.89 (0.72-1.10). For vitamin D, HRs trended toward reduction for RA 0.67 (0.37- 1.21), PMR 0.69 (0.46-1.03) and psoriasis 0.57 (0.33-0.99). For n-3 fatty acids, HRs trended toward reduction for RA 0.55 (0.30-1.10) and AITD 0.61 (0.33-1.12). Vitamin D's effect on AD incidence was stronger in those with body mass index (BMI) < 25 (HR 0.65, 0.44-0.96) than ≥ 25 kg/m^2 (p interaction 0.01).
Conclusion: Supplementation for 5.3 years with 2000 IU/day vitamin D (compared to placebo), followed by 2 years of observational follow-up, significantly reduced overall incident AD by 21% in older adults. HRs for RA, PMR and psoriasis trended toward reduction with vitamin D, with stronger effect in those with normal BMI. Supplementation with 1000 mg/day n-3 fatty acids did not significantly reduce total AD.

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[1] Hahn J *et al*, BMJ, 2022 Jan 26;376: e066452.

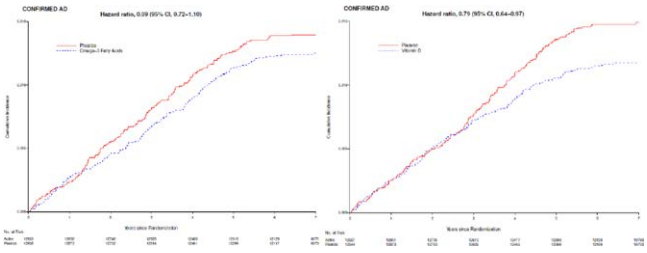

Figure 1.

Table 1. Hazard Ratios for Primary and Secondary Endpoints, by Randomized Assignment to Vitamin D/Placebo (Left), N-3 Fatty Acids/Placebo (Right)[a]

Endpoint	Vitamin D_3 (N=12,927)	Placebo (N=12,944)	Hazard Ratio (95% CI)	p	N-3 Fatty Acids (N=12,933)	Placebo (N=12,938)	Hazard Ratio (95% CI)	p
Primary: Confirmed AD	156	198	**0.79 (0.64-0.97)**	**0.03**	167	187	0.89 (0.72-1.10)	0.27
Secondary:								
Confirmed + probable AD	265	321	**0.83 (0.70-0.97)**	**0.02**	271	315	0.86 (0.73-1.01)	0.06
Excluding subjects with any pre-randomization AD								
Confirmed AD	127	162	**0. 79 (0.62-0.99)**	**0.04**	141	148	0.95 (0.75-1.20)	0.66
Confirmed + probable AD	211	270	**0. 78 (0.65-0.94)**	**0.007**	232	249	0.93 (0.78-1.11)	0.41
Excluding first 2 years follow-up								
Confirmed AD	86	130	**0.66 (0.50-0.87)**	**0.003**	104	112	0.92 (0.71-1.21)	0.56
Confirmed + probable AD	147	205	**0.72 (0.58-0.89)**	**0.002**	172	180	0.95 (0.77-1.17)	0.63
Individual AD[b]								
RA	18	27	0.67 (0.37-1.21)	0.18	16	29	0.55 (0.30-1.01)	0.06
PMR	39	57	0.69 (0.46-1.03)	0.07	46	50	0.92 (0.61-1.37)	0.67
AITD	27	18	1.50 (0.82-2.71)	0.19	17	28	0.61 (0.33-1.12)	0.11
Psoriasis	20	35	**0.57 (0.33-0.99)**	**0.05**	34	21	1.62 (0.94-2.79)	0.08

[a]Analyses from Cox regression models controlled for age, sex, race, and other (n-3 fatty acid or vitamin D) randomization group [b]Confirmed AD.

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OP0039

RISK OF ARRHYTHMIA AMONG NEW USERS OF HYDROXYCHLOROQUINE: A LONGITUDINAL POPULATION-BASED COHORT STUDY ON NEWLY DIAGNOSED RHEUMATOID ARTHRITIS AND SYSTEMIC LUPUS ERYTHEMATOSUS PATIENTS

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Background: Previous findings on hydroxychloroquine (HCQ) use and the risk of arrhythmia are contradictory and low-level evidence-based results. Additional research is required to evaluate the safety profile of HCQ to arrhythmia in managing rheumatoid arthritis (RA) and systemic lupus erythematosus (SLE).
Objectives: To assess the association between HCQ initiation and risk of incident arrhythmia among newly diagnosed RA and SLE patients.
Methods: All patients with incident RA or SLE and no arrhythmic events or anti-arrhythmic medications and no HCQ use prior to disease index date in British Columbia, Canada, between January 1997 and March 2015 were identified using administrative databases. HCQ initiator and HCQ non-initiator groups were identified and matched 1:1 by propensity scores using baseline confounders on demographics including presence of RA or SLE disease and duration of disease prior to the index date of HCQ initiators or non-initiators, comorbidities, other medications, and healthcare utilization. Matching was done within the same calendar year to account for a potential secular trend in HCQ use and risk of arrhythmia. Outcomes were any new arrhythmias, atrial fibrillation, abnormal electrocardiogram including prolonged QT syndrome and conduction disorder, and other unspecified arrhythmias during follow-up. We used Cox proportional hazard models with death as a competing event to assess the association of HCQ initiation and the outcomes.
Results: We identified 11,518 HCQ initiators (10,655 RA and 863 SLE patients, mean ± SD age 55.9 ± 15.1 years, 76.1% female) and 11,518 HCQ non-initiators (10,639 RA and 879 SLE patients, mean ± SD age 56.0 ± 16.2 years, 76.4% female) after 1:1 propensity score matching. Over the mean follow-up of eight years, there were 1,610 and 1,646 incident arrhythmias in the HCQ initiator and non-initiator groups, respectively. The crude incidence rates of arrhythmia were 17.5, and 18.1 per 1,000 person-years, respectively. Cumulative risk of incident arrhythmia remained similar for both groups. (Figure 1). Adjusted hazard ratio (aHR) of incident arrhythmia from the Cox proportional hazard model for HCQ initiators was 0.99 (95% CI: 0.92-1.06) compared to non-initiators (Table 1). The corresponding aHRs for HCQ initiators in subtypes of arrhythmia – atrial fibrillation, abnormal electrocardiogram, and other unspecified arrhythmias were 0.95 (95% CI: 0.84-1.06), 1.04 (95% CI: 0.87-1.26), and 0.96 (95% CI: 0.86-1.08), respectively.

Table 1. Incident arrhythmias of any type among RA and SLE patients initiating HCQ prescription compared with HCQ non-initiators

	HCQ initiator	HCQ non-initiator
Participants (number)	11,518	11,518
Mean follow-up (years)	8.00	7.89
Events (number)	1,610	1,646
Crude incidence rate per 1000 person-years	17.48	18.12
Unadjusted HR (95% CI)	0.98 (0.91-1.05)	1.00 (reference)
Adjusted# HR (95% CI)	0.99 (0.92-1.06)	1.00 (reference)

Abbreviations: **HCQ**, hydroxychloroquine; **HR**, hazard ratio.#The multivariable Cox proportional hazard model was adjusted for baseline confounders on demographics, comorbidities, medications, and healthcare utilization.

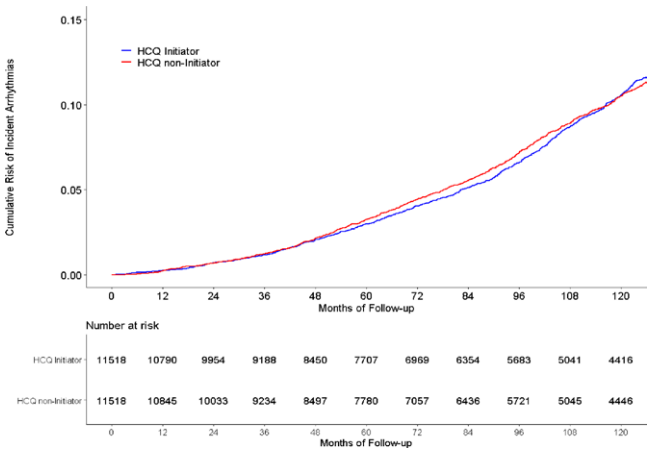

Figure 1. Cumulative risk of incident arrhythmias for HCQ initiators and non-initiators over the follow-up time.

Conclusion: There is no increased risk of any type of arrhythmia among new users of HCQ in RA and SLE patients. We believe the results of this large cohort study will add to the confidence with which HCQ can be used in RA and SLE management.
Disclosure of Interests: None declared.
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In dialogue with the expert: axSpA and Sjögren's syndrome

OP0040-PARE

THE WEBINAR SERIES FOR THE PATIENTS "PREGNANCY AFTER DIAGNOSING ANKYLOSIS SPONDYLITIS"

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Background: Having been diagnosed with ankylosis spondylitis (AS), 68,2% of females in Russia reconsider their plans for pregnancy, with 13% giving up motherhood altogether out of fear for their own and their child's potential health problems. However, most females allow pregnancy while experiencing emotional discomfort and anxiety[1].
Objectives: To shed more light on the mutual influence of AS and pregnancy, AS pregnancy outcomes, clinical course of AS as well as medication options during AS and lactation.
Methods: From 03/2021 to 12/2021 an on-line series of eight webinars was conducted together with the patients' Russian ankylosing spondylitis association. Each webinar included lectures of one or two rheumatologists and an obstetrician; furthermore, the series included the presentations of a physical therapy instructor (with the demonstration of exercises) and of a breast-feeding specialist. After the lecture each speaker answered the audience's questions. Topics of rheumatologists' lectures were "AS and pregnancy: problem introduction", "What do we know about AS genetics", "Features of pregnancy planning" (included therapy issues for men with AS who are planning to father a child), "Rheumatologist prenatal and postnatal care" (included the analysis of AS clinical manifestations such as potential changes in back pain type),"- Contemporary approaches to AS pregnancy treatment". A brochure for the patients with the main provisions of the lectures had been developed in support of the series.