Table 1. In-group comparison before and after the study

	Before Median (IQR 25/75)	After Median (IQR 25/75)	p
Exercise Group (n=21)			
Peak Power (W)	354.73 (267.59/471.55)	441.3 (295.2/636.9)	**0.002***
Peak Power (W/kg)	6.74 (5.44/8.94)	7.7 (6.4/9.7)	**0.001***
Average Power (W)	291.5 (188.78/359.61)	360.0 (220.4/446.4)	**0.001***
Average Power (W/kg)	5.54 (4.07/6.88)	6.0 (4.8/7.4)	**0.002***
Control Group (n=21)			
Peak Power (W)	355.57 (225.43/463.62)	366.7 (236.3/447.8)	0.259
Peak Power (W/kg)	6.69 (5.80/7.83)	7.3 (6.1/8.1)	0.232
Average Power (W)	261.04 (181.68/351.27)	284.8 (187.8/373.0)	0.050
Average Power (W/kg)	5.29 (4.75/5.85)	5.5 (5.0/6.1)	0.076

Wilcoxon Test. IQR: Interquartile Range; W: watt; W/kg: watt/kilogram; *p<0.05.

Table 2. The differences in the groups after 8 weeks

	Exercise Group (n=21) Median (IQR 25/75)	Control Group (n=21) Median (IQR 25/75)	p
ΔPeak Power (W)	65.1 (23.8/107.1)	24.5 (-15.6/39.4)	**0.009***
ΔPeak Power (W/kg)	0.9 (0.3/1.6)	0.3 (-0.3/0.6)	**0.007***
ΔAverage Power (W)	41.4 (9.9/78.7)	17.3 (5/31.3)	**0.019***
ΔAverage Power (W/kg)	0.6 (0.3/1.3)	0.2 (-0.1/0.5)	**0.024***

Mann-Whitney U Test. IQR: Interquartile Range; Δ: Delta; W: watt; W/kg: watt/kilogram; *p<0.05.

Conclusions: The present study is the first study focusing on improving anaerobic capacity in children with JIA. According to our results, an 8-week water exercise program which is performed at the weekends might be beneficial to improve anaerobic exercise capacity in children with JIA.
Disclosure of Interest: None declared
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WEDNESDAY, 14 JUNE 2017

Assessment and management of osteoporosis

OP0010 EFFECT OF DENOSUMAB COMPARED WITH RISEDRONATE IN GLUCOCORTICOID-TREATED INDIVIDUALS: RESULTS FROM THE 12-MONTH PRIMARY ANALYSIS OF A RANDOMIZED, DOUBLE-BLIND, ACTIVE-CONTROLLED STUDY

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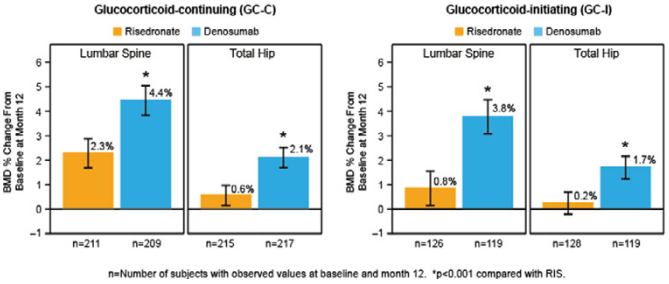
Background: Glucocorticoid (GC)-induced osteoporosis (GIOP) remains the most common secondary cause of osteoporosis. Despite approved therapies, many subjects do not receive GIOP prevention or treatment. There is increased RANKL and decreased osteoprotegerin (OPG) expression in patients with GIOP. Denosumab (DMAb) is a monoclonal antibody to RANKL. This study was designed to assess the safety and efficacy of DMAb compared with risedronate (RIS) in GC-treated individuals, in whom treatment guidelines advocate a GIOP intervention.
Objectives: The primary objective was to demonstrate, in separate GC-continuing (GC-C) and GC-initiating (GC-I) subpopulations, that DMAb was not inferior to RIS with respect to percentage change from baseline (%Δ) in lumbar spine (LS) bone mineral density (BMD) at 12 months. Secondary objectives were to assess superiority of DMAb over RIS with respect to %Δ in LS and total hip (TH) BMD at 12 months.
Methods: This was a phase 3, randomized, double-blind, double-dummy, active-controlled study to evaluate DMAb vs. RIS in GC-treated individuals for 24 months. Eligible subjects were women and men ≥18 yrs receiving GC therapy at a dose ≥7.5 mg prednisone daily or its equivalent for ≥3 months or <3 months prior to screening (GC-C and GC-I, respectively). All subjects <50 yrs were required to have a history of osteoporotic fracture. GC-C subjects ≥50 yrs were required to have a LS, TH, or femoral neck BMD T-score ≤-2.0; or a T-score ≤-1.0 with a history of osteoporotic fracture. Subjects were randomized 1:1 to SC DMAb 60 mg every 6 months or oral RIS 5 mg daily for 24 months. Subjects were to receive daily calcium (≥1000 mg) and vitamin D (≥800 IU) supplementation. Primary outcome was %Δ in LS BMD at 12 months (non-inferiority in GC-C and GC-I). Secondary outcomes included %Δ in LS and TH BMD at 12 months (superiority). The study remains blinded and is ongoing.
Results: A total of 795 subjects (505 GC-C and 290 GC-I) enrolled in the study. Baseline characteristics were balanced between treatment groups (Table). Non-inferiority and superiority with DMAb were demonstrated for both the GC-C and GC-I subpopulations, as indicated by significantly greater BMD gains compared with RIS at the LS and TH in both subpopulations (Figure). The incidences of adverse events (AEs) and serious AEs, including serious AEs of infection, as well as fracture, were similar between treatment groups and consistent with the known safety profile of DMAb.

Table. Baseline Characteristics

	Glucocorticoid-continuing (GC-C)		Glucocorticoid-initiating (GC-I)	
	Risedronate N=252	Denosumab N=253	Risedronate N=145	Denosumab N=145
Sex – n (%)				
Male	67 (26.6)	68 (26.9)	52 (35.9)	52 (35.9)
Female	185 (73.4)	185 (73.1)	93 (64.1)	93 (64.1)
Age (years) – mean (SD)	61.3 (11.1)	61.5 (11.6)	64.4 (10.0)	67.5 (10.1)
Medical conditions of interest – n (%)				
Rheumatoid arthritis	118 (46.8)	96 (37.9)	43 (29.7)	48 (33.1)
Polymyalgia rheumatic	18 (7.1)	20 (7.9)	52 (35.9)	50 (34.5)
Systemic lupus erythematosus	16 (6.3)	15 (5.9)	4 (2.8)	2 (1.4)
Daily prednisone-equivalent dose (mg) – mean (SD)	11.13 (7.69)	12.29 (8.09)	15.61 (10.25)	16.57 (13.01)
25 (OH) vitamin D (ng/mL) – median (Q1, Q3)	28.0 (23.6, 36.3)	29.2 (24.2, 37.6)	28.6 (24.2, 36.4)	28.8 (23.6, 36.0)
BMD T-score – mean (SD)				
Lumbar spine	-1.96 (1.38)	-1.92 (1.39)	-1.06 (1.57)	-0.92 (1.86)
Total hip	-1.56 (0.96)	-1.66 (0.96)	-0.98 (1.07)	-1.14 (1.00)

Figure. BMD Percentage Change From Baseline at Month 12



n=Number of subjects with observed values at baseline and month 12. *p<0.001 compared with RIS.

Conclusions: DMAb significantly increased BMD more than RIS at the spine and hip at 12 months. The overall safety profile was similar between treatment groups. DMAb has the potential to become another treatment option for patients newly initiating or continuing GC who are at risk for fracture.
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Systematic literature review: the link from science to clinical practice

OP0011 DOES A VERY EARLY THERAPEUTIC INTERVENTION IN VERY EARLY ARTHRITIS / PRE-RHEUMATOID ARTHRITIS PATIENTS PREVENT THE ONSET OF RHEUMATOID ARTHRITIS: A SYSTEMATIC REVIEW AND METANALYSIS

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Background: Recent progress in the understanding of rheumatoid arthritis (RA) pathogenesis leads to growing interest in the concept of pre-RA, a clinical stage in which very early intervention could be more efficacious.
Objectives: To assess the efficacy of very early therapeutic interventions in pre-RA patients, i.e., with either undifferentiated arthritis, or ACPA-positive arthralgia/arthritis (ie, very early RA, VERA), through a systematic literature review (SLR) and meta-analysis (MA).
Methods: The SLR was performed following Cochrane guidelines. The search used "undifferentiated arthritis" or "very early rheumatoid arthritis" (VERA) associated with "therapy" or "treatment", and was limited to randomized controlled trials (RCTs) published in English over the last five years. It was conducted in Pubmed, Embase and Cochrane RCT databases, as well as EULAR and ACR congress abstracts of the last two years. Two independent readers (SH, BH) extracted the following data through a standardized form: study quality, patient status at baseline (either undifferentiated arthritis or VERA), the type of intervention, and disease characteristics over time as well as occurrence of RA.