

Results EudraCT: Imaging, patient reported outcome, biochemical analysis assessed at baseline and week 36 in the pamidronate and placebo group

Pamidronate					Placebo				Group difference (pamidronate vs placebo)	
	Baseline	W36	Difference		Baseline	W36	Difference		P#	P*
			Mean	(SD) P			Mean (sd)	P		
Imaging										
Disease activity ACW (WBMRI)										
Activity score	4.8 (2.2)	2.5 (1.6)	2.3 (1.5)	0.01	4.2 (5.4)	4.2 (4.0)	0 (2.3)	1.00	0.04	0.09
Chronicity score	4.7 (0.5)	5.1 (1.1)	0.5 (1.0)	0.30	7.2 (6.8)	7.2 (6.8)	0	-	0.27	0.55
Disease activity ACW (CT)										
Chronicity score	15.3 (7.9)	15.8 (7.5)	0.5 (0.84)	0.20	14 (11.2)	14.2 (11.2)	0	-	0.17	-
Disease activity score spine (WBMRI) **										
Activity score	27	20	7	-	10.6 (5.9)	10.8 (8.4)	0.2 (3.4)	0.90	0.06	-
Chronicity score	26	24	2	-	15 (3.3)	15.8 (2.9)	0.8 (0.84)	0.10	0.02	-
Patient reported outcome										
VAS										
VAS pain	38 (23)	19 (17.9)	19 (21)	0.08	49 (32)	47 (32.5)	2(17)	0.76	0.13	0.23
VAS global	32 (22.3)	13 (17.9)	18 (14)	0.03	53 (31.0)	45 (33.7)	8(15)	0.25	0.24	0.71
Biochemical analysis										
Biomarkers of bone turnover (ug/L)										
CTX	0.26 (0.13)	0.16 (0.07)	0.10 (0.12)	0.09	0.40 (0.99)	0.40 (0.21)	0 (0.12)	0.96	0.21	0.17
BAP	17.3 (3.8)	11.6 (2.1)	5.7 (2.7)	<0.01	23.4 (5.9)	22.3 (6.6)	1.1 (6.4)	0.68	0.10	0.06
P1NP	75.6 (50.0)	24.2 (8.8)	51.5 (43.1)	0.03	84.2 (34.9)	65.8 (35.4)	18.3 (32.0)	0.22	0.13	0.49
Osteocalcin	26.8 (19.4)	14.5 (5.5)	12.3 (15.4)	0.11	31.8 (13.3)	27.8 (11.1)	4 (8.4)	0.30	0.25	0.57
OPG	2150 (998)	2506 (1867)	357 (803)	0.33	1668 (445)	1680 (292)	12 (300)	0.92	0.98	0.55
Biomarkers of inflammation (ng/L)										
IL-6	0.63 (0.28)	0.53 (0.24)	0.11 (0.13)	0.10	1.25 (0.83)	0.75 (0.29)	0.51 (0.59)	0.09	0.11	0.13
TNF-α	2.09 (0.67)	2.18 (0.57)	0.10 (0.44)	0.62	1.86 (1.00)	2.25 (0.54)	0.39 (0.79)	0.28	0.42	0.55
IL-1β	0.11 (0.11)	0.11 (0.09)	0.001 (0.16)	0.99	0.16 (0.11)	0.10 (0.56)	0.07 (0.13)	0.25	0.24	0.33
IL-22	0.74 (0.59)	1.45 (1.02)	0.71 (0.75)	0.07	0.80 (0.80)	1.15 (0.90)	0.35 (0.67)	0.26	0.87	0.97
Values at baseline and w36 are mean (standard deviation). Paired t-test was used to test the mean differences between baseline and week 36 and is given as mean difference (sd) and p-value.										
P#: P-value testing pamidronate vs. placebo mean group difference (difference from baseline to week 36) using unpaired t-test .										
P*: P-value testing the hypothesis of parallel mean curves between (pamidronate vs placebo baseline and week 1, 4, 12, 24 and 36) by multivariate regression analysis										
ACW anterior chestwall, WBMRI whole-body magnetic resonance imaging, CT computed tomography CTX: C-terminal telopeptide of type I collagen, BAP: bone-specific alkaline phosphatase, P1NP: procollagen type 1 N-terminal propeptide, OPG: Osteoprotegerin IL: Interleukin, TNF-α: tumor necrosis factor-α										