

October 2023

Liposphere – Enabling smooth articulation of joints

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First-In-Human clinical trial



// Single intra-articular injection into the target knee
 // Volume of injection of 4ml

Screening	1-month visit	3-month visit	6-month visit
IA injection NRS KOOS	NRS KOOS	NRS KOOS	NRS KOOS

NRS <> Numeric Rating Scale, 0 to 10 cm scale



KOOS <> Knee injury & Osteoarthritis Outcome Score



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First In Human Study – Parameters and Outcome

Primary outcome

No related adverse events *
have been reported by patients during the study!

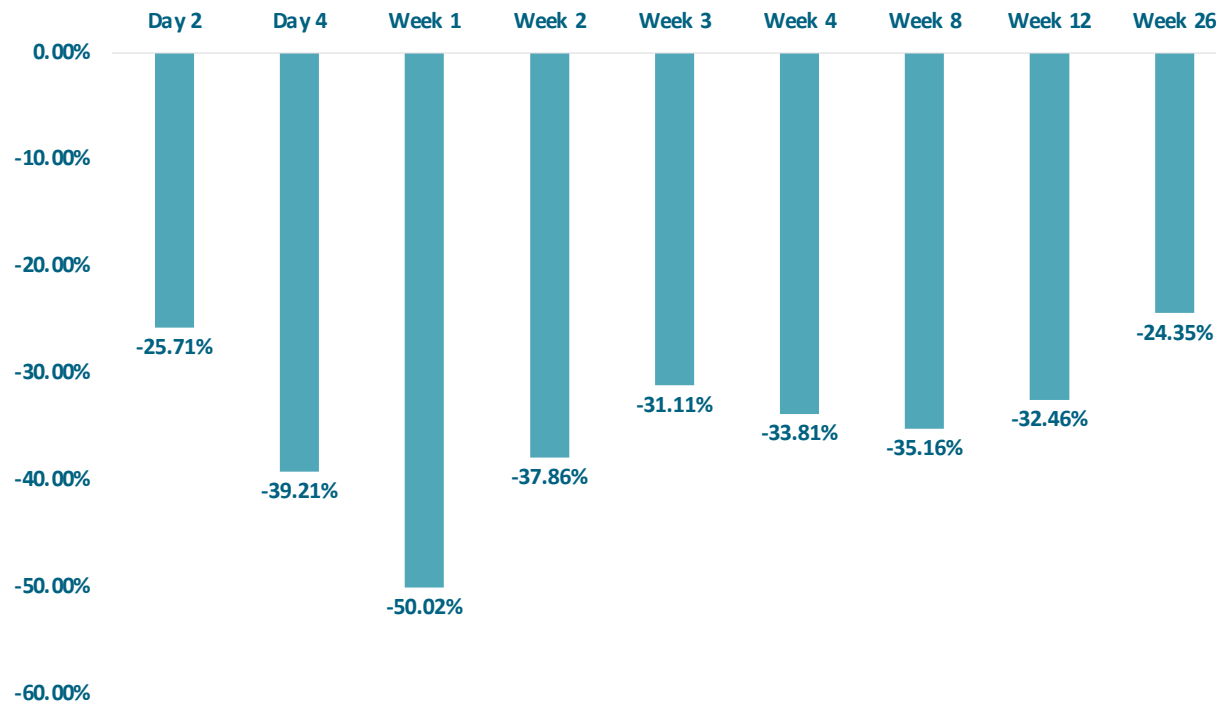
*Joint pain, Joint swelling, Joint stiffness,
Joint disorder, Joint infection

Baseline Demographic and Clinical Parameters

	n=18	
	Mean	SD
Age	69.28	6.22
Weight	84.06	12.6
Height	167.22	9.9
BMI	30.01	3.59
Angulation	5.44	1.92
Knee flexion	116.11	7.78
Knee extension	0.28	1.18
VAS	6.66	1.71
OA Kellgren- Lawrence grade		
I	1	
II	1	
III	16	
Sex		
Female	6	
Male	12	

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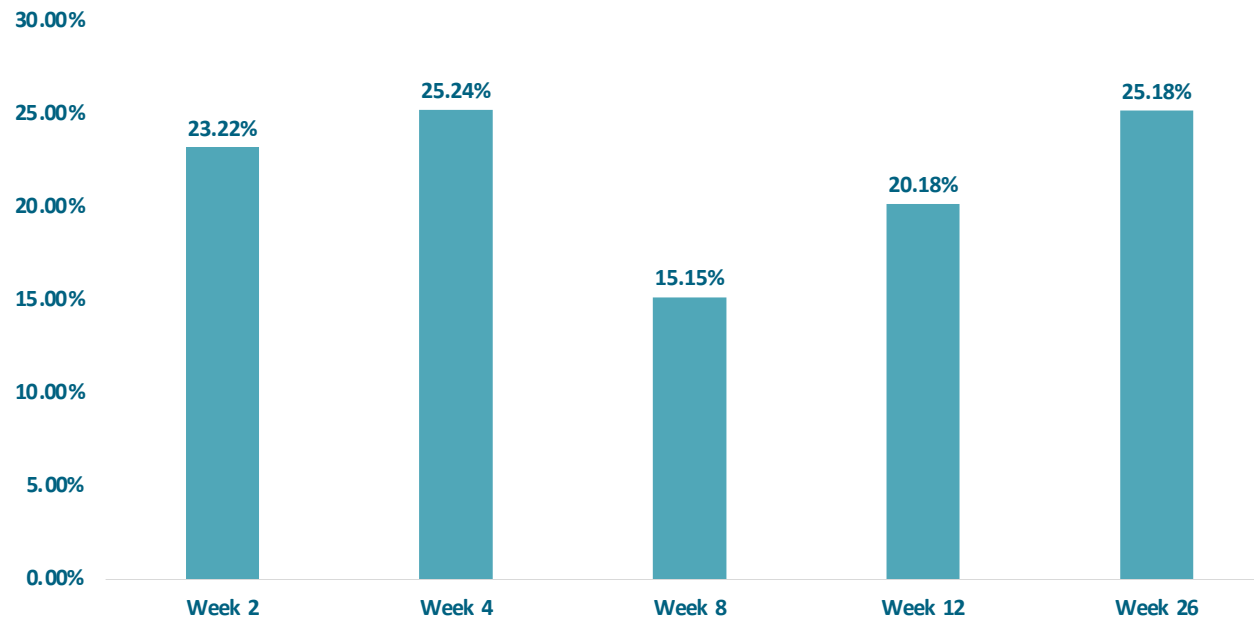
Effect of injection on pain - NRS



Results showed a significant decrease in NRS (Friedman X² = 35.08, p < .001). Specifically, results showed a significant decrease between NRS at Day 1 Baseline and NRS at Day 4 (p=.002), Week 1 (p=.001), Week 2 (p<.001), Week 3 (p=.005), week 4 (p=.008), week 8 (p=.003), week 12 (p=.011) and week 26 (p=.012).

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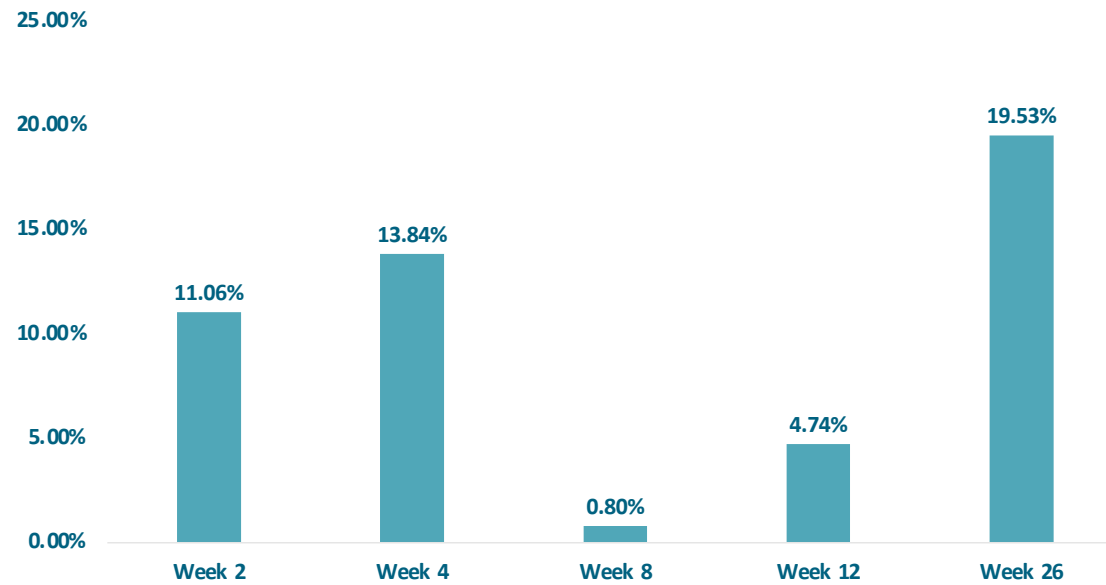
Effect of injection on KOOS - symptoms



A significant change has been detected between Baseline and week 2 ($p=.02$) and week 4 ($p=.03$).

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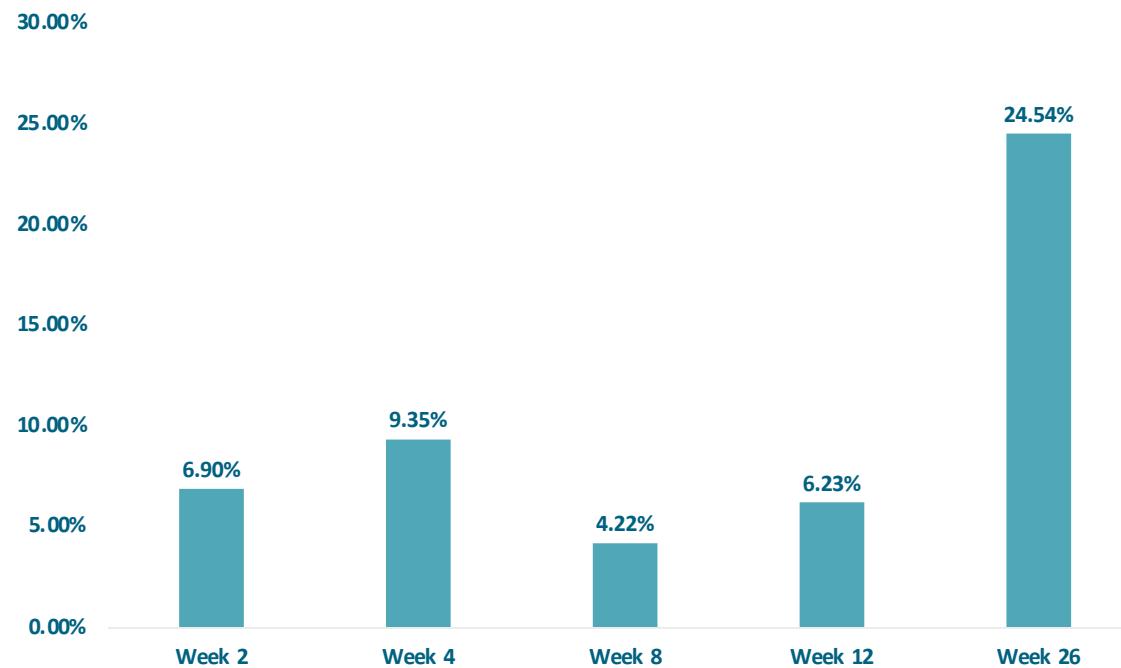
Effect of injection on KOOS - pain



A significant change has been detected between the Baseline and week 4 ($p=.01$).

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Effect of injection on KOOS - ADL

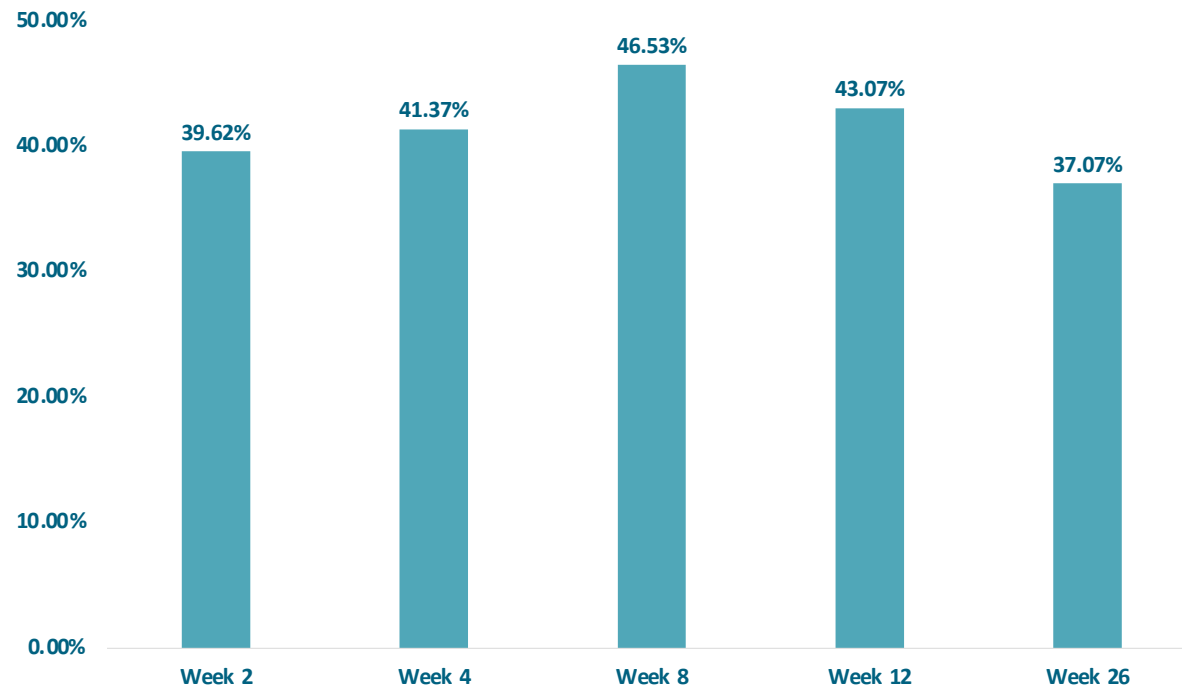


Results showed a significant increase in KOOS ADL (Friedman X2 = 12.95, p = .024). Specifically, results showed a significant increase between KOOS ADL at V1 and KOOS ADL at week 26 (p=.039).

ADL: Activities of Daily Life

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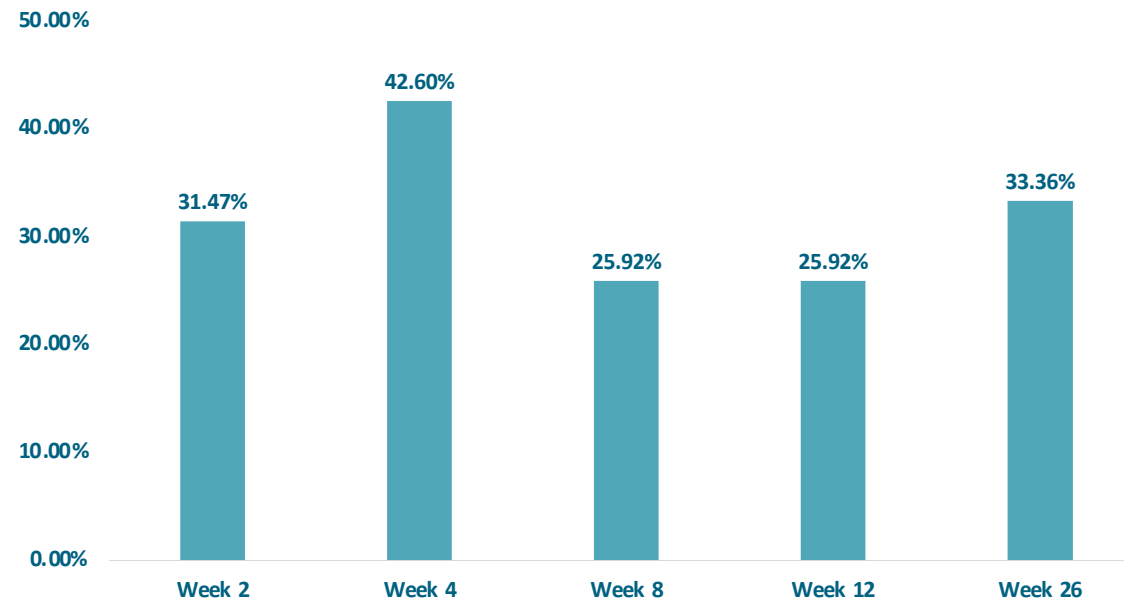
Effect of injection on KOOS - Sport



Results showed a significant increase between KOOS sport on day 1 and KOOS sport at week 2 ($p=.02$), week 12 ($p=.05$), and week 26 ($p=.03$).

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Effect of injection on KOOS - Sport



A single significant change was found between KOOS QOL at Baseline and Week 8 ($p=.05$).

QOL: Quality of Life



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