
Next Generation Regeneration

Knee Biologics



Preliminary 4 Yr KOA Study Results

Intra-articular Gold Induced Cytokine (GOLDIC®) Injections Therapy in Patients with Osteoarthritis of Knee Joint: A Clinical Study

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Abstract:

Background: We developed a novel technique of cultivating autologous blood with gold particles; then separated gold particles and cells from the serum and injected the conditioned serum into knee joints. The aim of our study was to explore the safety and efficacy of this novel approach in the treatment of degenerative knee joint disorders.

Materials & Methods: In a prospective case study, 64 consecutive patients (89 knees) with radiologically proven osteoarthritis of knee joint were treated with four intra-articular GOLDIC® injection therapy. All the patients were evaluated by WOMAC & KOOS score before injection and at 1, 3, 6, 12, 24 and 48 (T1-T6) month follow-up after the injections. Statistical analysis was performed to evaluate the significance of sex, age, grade of OA and BMI. The intra-articular gelsolin level was analysed in patients with effusion.

Results: All KOOS and WOMAC scores showed statistically significant improvement in mean for nearly all follow-up timepoints compared to T0, pre treatment ($P < 0.05$). The intra-articular gelsolin level showed a significant increased level after the GOLDIC® injections and a simultaneous reduction of effusion.

Conclusion: This is the first innovative Gold Induced Cytokine (GOLDIC®) intra-articular injection therapy for osteoarthritis of the knee joint in humans. The initial results demonstrate that the treatment regimen is safe, less expensive, patient friendly and has greater compliance due to one-time harvesting of blood with only 4 weekly injections. The treatment has the potential to reduce pain, improve knee function and quality of life over a long period of time in comparison to other blood-based therapies. The upregulation of gelsolin and presence of other growth factors in GOLDIC® appears to be contributing in restoration of overall joint homeostasis. Despite the promising early clinical results, randomised controlled studies with long term follow-up are required to validate the real potential of GOLDIC® and to compare these good results to other blood-based platforms.

Statistical Analysis - KOOS & WOMAC Score

KOOS_ADL	Mean	65,7	75,1	78,2	80,3	83,1	78,4	76,4
	StdDeviation	18,7	16,2	17,9	16,1	14,8	16,3	21,7
	Two Way ANOVA Prob	0,000						
	Paired t-Test Prob (2-tail) vs T0		0,006	0,006	0,002	0,000	0,018	0,063
KOOS_PAIN	Mean	60,3	72,4	76,1	80,9	81,0	76,3	75,0
	StdDeviation	18,4	18,0	16,9	14,4	13,3	15,4	19,9
	Two Way ANOVA Prob	0,000						
	Paired t-Test Prob (2-tail) vs T0		0,001	0,001	0,000	0,000	0,004	0,012
KOOS_QOL	Mean	36,5	46,5	52,0	56,8	57,8	53,5	53,0
	StdDeviation	20,9	25,3	27,2	24,2	23,1	22,9	26,2
	Two Way ANOVA Prob	0,000						
	Paired t-Test Prob (2-tail) vs T0		0,013	0,002	0,000	0,000	0,002	0,005
KOOS_SPORT_REC	Mean	35,4	43,2	49,0	56,6	57,2	53,0	51,8
	StdDeviation	26,6	30,6	28,3	28,9	30,8	29,2	34,6
	Two Way ANOVA Prob	0,000						
	Paired t-Test Prob (2-tail) vs T0		0,070	0,007	0,001	0,001	0,014	0,027
KOOS_SYMPTOMS	Mean	68,9	75,3	81,4	84,7	84,1	79,1	76,9
	StdDeviation	21,1	19,1	13,3	13,6	14,3	17,2	20,4
	Two Way ANOVA Prob	0,000						
	Paired t-Test Prob (2-tail) vs T0		0,037	0,001	0,000	0,001	0,027	0,101
original_WOMAC_FUNCTION	Mean	23,3	16,9	14,8	13,4	11,5	14,7	16,1
	StdDeviation	12,7	11,0	12,1	10,9	10,0	11,1	14,7
	Two Way ANOVA Prob	0,000						
	Paired t-Test Prob (2-tail) vs T0		0,006	0,006	0,002	0,000	0,018	0,063
original_WOMAC_PAIN	Mean	7,0	4,5	3,7	3,1	3,0	4,0	4,3
	StdDeviation	3,9	3,1	3,1	2,8	2,3	2,9	4,1
	Two Way ANOVA Prob	0,000						
	Paired t-Test Prob (2-tail) vs T0		0,000	0,001	0,000	0,000	0,006	0,030
original_WOMAC_STIFFNESS	Mean	3,1	2,5	1,9	1,7	1,5	1,8	2,2
	StdDeviation	2,5	2,5	1,9	1,9	1,8	2,0	2,3
	Two Way ANOVA Prob	0,000						
	Paired t-Test Prob (2-tail) vs T0		0,074	0,002	0,002	0,001	0,006	0,078

Kolmogorov-Smirnov-Test shows no significant deviation compared to a normal distribution; red probabilities mark significant mean differences; $\alpha < 0,05$

Table 1 : Statistical analysis of KOOS and WOMAC-score

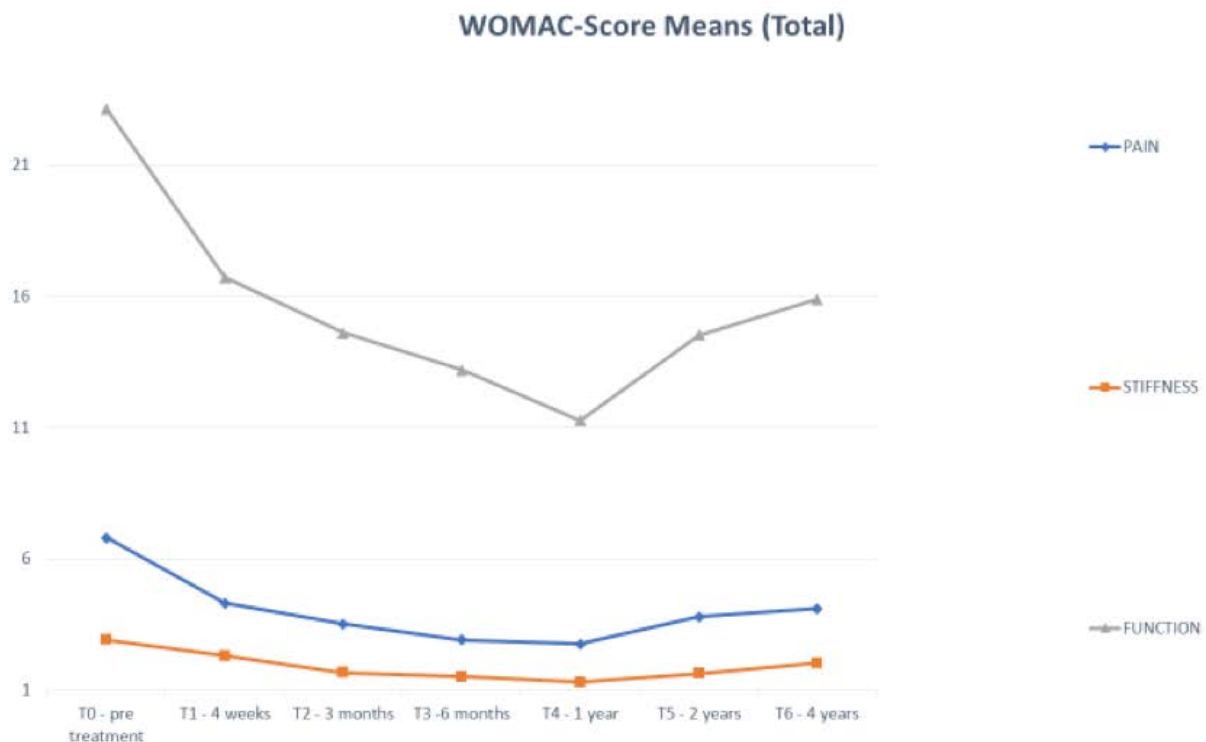


Fig.1: Demonstration of overall WOMAC-Score mean at all time points

Statistical Analysis - KOOS & WOMAC Score

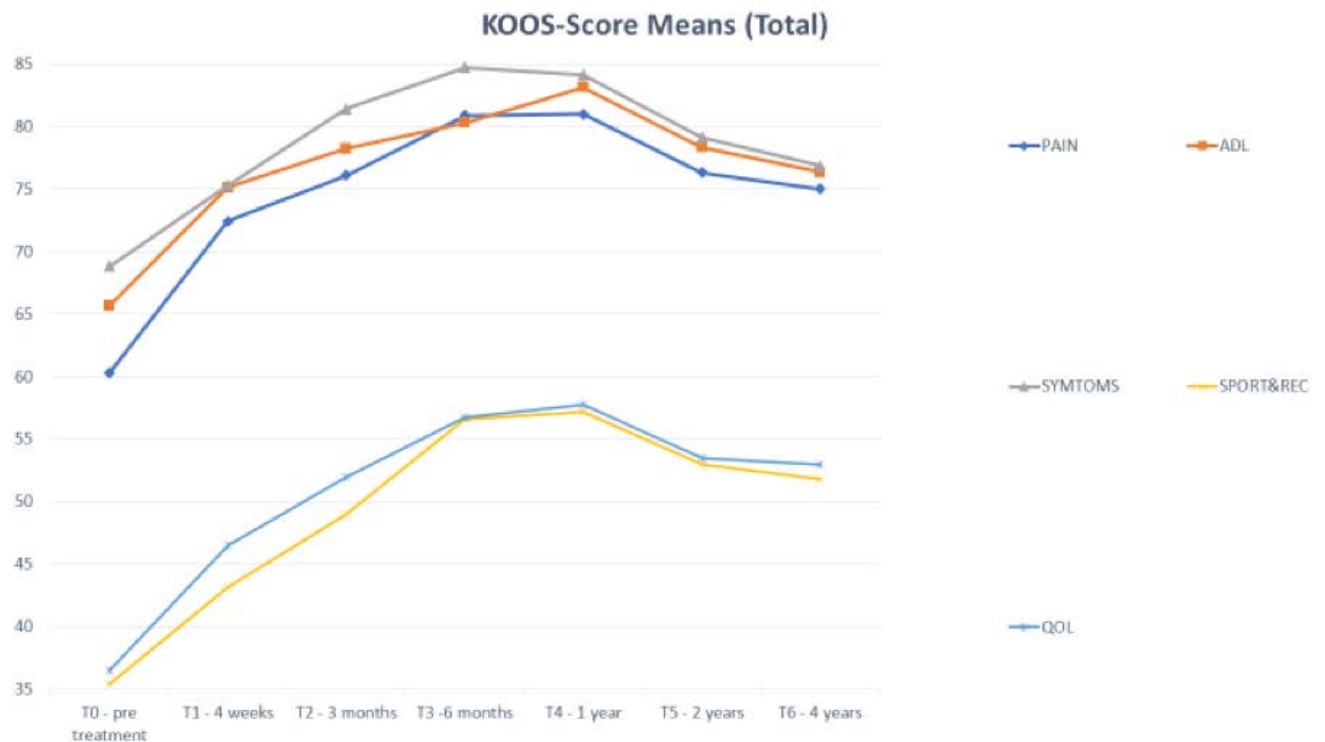


Fig.2: Demonstration of overall KOOS-Score mean at all time points

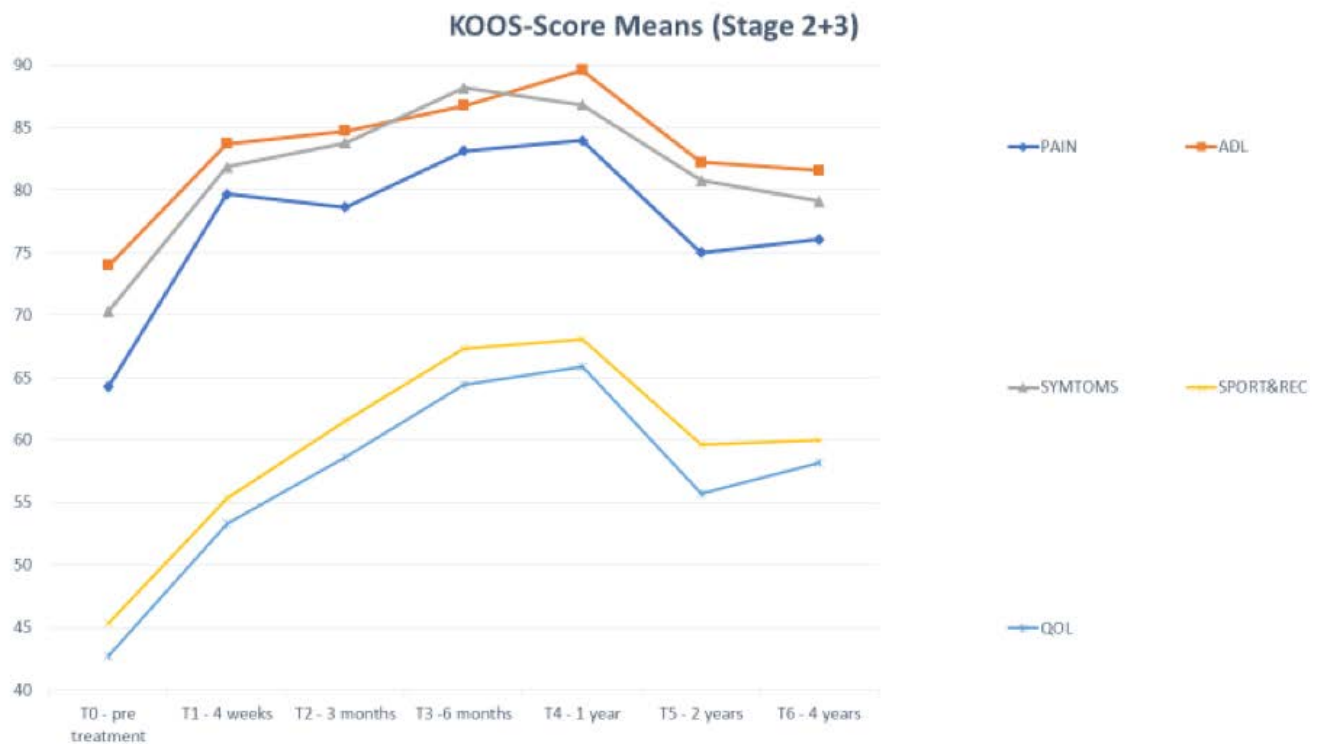


Fig.3: Demonstration of overall KOOS-Score mean with stage 2-3 patients at all time points

Statistical Analysis - KOOS & WOMAC Score



Fig.4: Demonstration of overall KOOS-Score mean with stage 4 patients at all time points

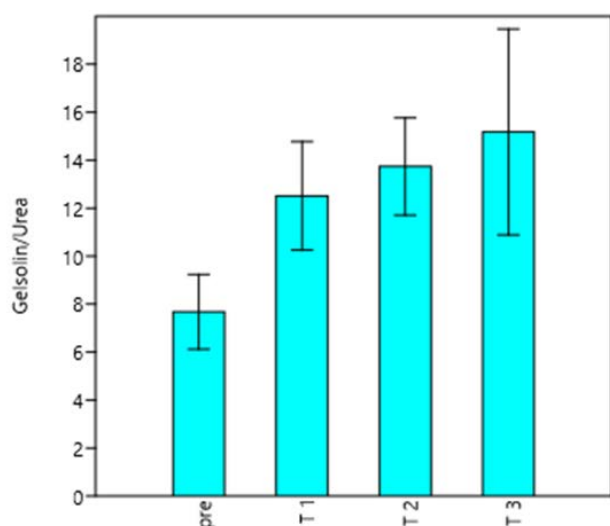


Fig.5: Demonstration of Gelsolin/Urea levels at the different timepoints: pre=before treatment, T1= between 3 to 6 days after first GOLDIC injection, T2= between 8 and 11 days after the second injection and T3= between 13 and 15 days after the third injection.

GOLDIC Related Literature

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