A PHASE II STUDY ASSESSING THE PRELIMINARY OUTCOME FOR EFFICACY OF ALLOGENIC UMBILICAL CORD DERIVED MESENCHYMAL STEM CELLS IN PATIENT WITH KNEE CARTILAGE INJURY .

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INTRODUCTION:

The allogenic umbilical derived mesenchymal stem cells (UC-MSCs) have potential therapeutic option for knee articular cartilage injury ICRS grade III or IV. The aim of this study was to assess the efficacy of allogenic UC-MSCs versus Hyalorunic Acid 3D scaffold with bone marrow aspirate concentrate (BMAC).

MATERIALS & METHODS:

This is a two arm, prospective, randomized controlled, open label, phase II clinical trial in University Kebangsaan Malaysia Medical Center with outcome of six months follow-up period. 20 patients with symptom of knee chondral cartilage injury were randomize either receive allogenic UC-MSCs or hyaluronic acid 3D scaffold with autogenic BMAC injection. Both group will undergo arthroscopic knee chondral debridement surgery. Outcome of treatment will be compared during first, third- and sixth-month follow up assessed by VAS, KOOS and IKDC.

RESULTS & DISCUSSION:

These study show both groups had achieved significant improvement. Patinets under UC-MSCs injection show better improvement as shown in Table 1 and table 2 compare with those treated under BMAC group. These had suport the positive outcome in term of efficacy and capability of regenerative therapy trough differentiation into chondrogenic lineage, inducing proliferation and differentiation of chondrocyte progenitors, and modifying reaction of endogenous cells[1]. Ttreatment were proved to be safe with no serious adverse event reported other than additional donor site morbidity particularly in group of patients requiring BMAC[2]

Comparison between pre- and post-treatment in UC-MSCs Group with baseline	Sig. (2-tailed)				
			95% Confidence Interval of the Difference		
	Mean	Std. Deviation	Lower	Upper	P value
IKDC at 1 month	-5.28000	16.14592	-16.83009	6.27009	.328
IKDC at 3 month	-21.61000	14.77140	-32.17682	-11.04318	.001
IKDC at 6 month	-28.27000	12.42507	-37.15836	-19.38164	.000
KOOS at 1 month	-12.400	16.008	-23.852	-.948	.037
KOOS at 3 month	-25.700	17.720	-38.376	-13.024	.001
KOOS at 6 month	-31.200	16.047	-42.679	-19.721	.000
VAS at 1 month	3.500	2.121	1.982	5.018	.001
VAS at 3 month	5.100	1.101	4.313	5.887	.000
VAS at 6 month	4.500	1.581	3.369	5.631	.000

Table 1. UC-MSCs group

Comparison between pre- and post-treatment in BMAC & 3D scaffold Group compare with baseline	Sig. (2-tailed)				
			95% Confidence Interval of the Difference		
	Mean	Std. Deviation	Lower	Upper	P Value
KDC at 1 month	-.12000	12.43854	-9.01800	8.77800	.976
IKDC at 3 month	-17.61000	15.24572	-28.51613	-6.70387	.005
IKDC at 6 month	-20.82000	14.57165	-31.24393	-10.39607	.001
KOOS at 1 month	-.100	12.741	-9.214	9.014	.981
KOOS at 3 month	-16.300	11.795	-24.738	-7.862	.002
KOOS at 6 month	-18.900	13.844	-28.803	-8.997	.002
VAS at 1 month	1.500	1.354	.531	2.469	.007
VAS at 3 month	2.900	2.424	1.166	4.634	.004
VAS at 6 month	3.100	1.792	1.818	4.382	.000

Table 2.BMAC group

CONCLUSION:

The injection of allogenic UC-MSCs shows improvement to overall symptoms and function as measured by VAS, KOOS and IKDC score. It also requires less knee surgery, reduces overall cost, and avoid donor-site morbidity. It does have a role to become as a standard treatment in patients with ICRS grade III and IV knee articular cartilage injury. Follow up study will be continue to get long term outcome.

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