Improvement of Quality of Life for advanced cancer patient with injection of complementary PG₂ - A Double Blind, Multi-Center, Randomized Phase IV Study

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Introduction

Quality of Life (QoL) was proposed as a survival predictor in advanced cancer patients. PG₂ injection was extracted and purified from Astragalus membranaceus. In Traditional Chinese medicine, Astragalus membranaceus is commonly used to treat the deficiency of qi (vital energy). We evaluated the efficacy of PG₂ injection in improving QoL in advanced cancer patient with or without palliative radiotherapeutic or chemotherapeutic treatments in this study.

Objectives

The aim of this study was to evaluate the effect of PG₂ injection on QoL in advanced progressed cancer patients under standard palliative care.

Methods

Patients with advanced cancer receiving standard palliative care were enrolled and randomized at a 1:1 ratio into two arms of PG₂ injection treatment: 500mg dose (500mg in 500ml saline, 3 times per week for 4 weeks) or 250mg dose (250mg in 500ml saline, 3 times per week for 4 weeks) for two cycles. Symptoms and Quality of Life Assessments were analyzed by 11 questions (SS11) from European Organization for Research and Treatment of Cancer QoL Questionnaire (EORTC QLQ-C30). Patients were divided into untreated, palliative chemotherapy treated, and palliative radiotherapy treated groups for analysis.

Results

Three hundred and ten patients were enrolled in this study. High and low doses of PG₂ injection significantly improved patients' appetite loss (p<0.0001, p=0.0004), fatigue (p<0.0001, p<0.0001), insomnia (p=0.0002, p<0.00001), and global QoL (p<0.0001, p<0.0001) after two cycles of treatments. Patients with or without therapeutic treatments were both analyzed.

Conclusions

PG₂ injection can significantly improve several indicators for QoL in advanced cancer patients without safety concern.

Figure 1. Study design

Table 1. Effect of PG₂ on ameliorating appetite loss

	Item Cycle / Visit	High Dose Arm (N=111)	Low Dose Arm (N=103)	Differences among Groups with 95% CI
Appetite Loss				
Cycle 1				
Baseline				
n		111	103	
Mean (SD)		54.65 (28.71)	56.95 (30.12)	(-10.23, 5.62)
Week 4 Change From Baseline				
n		109	103	
Mean (SD)		-8.26 (31.15)	-11.97 (34.57)	(-5.18, 12.62)
*P-value		0.0066	0.0007	
Cycle 2				
Week 4 Change From Baseline				
n		75	65	
Mean (SD)		-19.55 (32.00)	-15.90 (34.41)	(-14.76, 7.45)
*P-value		<0.0001	0.0004	

Table 2. Effect of PG₂ on relieving insomnia

	Item Cycle / Visit	High Dose Arm (N=111)	Low Dose Arm (N=103)	Differences among Groups with 95% CI
Insomnia				
Cycle 1				
Baseline				
n		111	103	
Mean (SD)		52.55 (33.20)	61.49 (32.59)	(-17.81, -0.06)
Week 4 Change From Baseline				
n		109	103	
Mean (SD)		-8.26 (33.07)	-18.45 (29.79)	(1.65, 18.73)
*P-value		0.0104	<0.0001	
Cycle 2				
Week 4 Change From Baseline				
n		75	65	
Mean (SD)		-16.00 (35.66)	-20.00 (31.07)	(-7.26, 15.26)
*P-value		0.0002	<0.0001	

Table 3. Effect of PG₂ on reducing fatigue

	Item Cycle / Visit	High Dose Arm (N=111)	Low Dose Arm (N=103)	Differences among Groups with 95% CI
Fatigue				
Cycle 1				
Baseline				
n		111	103	
Mean (SD)		73.17 (21.89)	74.00 (20.79)	(-6.59, 4.93)
Week 4 Change From Baseline				
n		109	103	
Mean (SD)		-16.00 (23.30)	-17.26 (25.12)	(-5.30, 7.81)
*P-value		<0.0001	<0.0001	
Cycle 2				
Week 4 Change From Baseline				
n		75	65	
Mean (SD)		-24.15 (29.36)	-22.90 (24.99)	(-10.43, 7.94)
*P-value		<0.0001	<0.0001	

Table 4. Effect of PG₂ on improving global health status

	Item Cycle / Visit	High Dose Arm (N=111)	Low Dose Arm (N=103)	Differences among Groups with 95% CI
Global Health Status				
Cycle 1				
Baseline				
n		111	103	
Mean (SD)		36.41 (18.97)	33.82 (17.77)	(-2.37, 7.55)
Week 4 Change From Baseline				
n		109	103	
Mean (SD)		9.71 (25.80)	9.87 (21.70)	(-6.63, 6.31)
*P-value		0.0002	<0.0001	
Cycle 2				
Week 4 Change From Baseline				
n		75	65	
Mean (SD)		16.33 (24.41)	16.54 (24.80)	(-8.45, 8.03)
*P-value		<0.0001	<0.0001	

Figure 2. Patients with low baseline NLR (<3) seemed to have better fatigue, insomnia, pain, and global health status improvement.