Supplementary Materials

Fish oil-enriched food for special medical purpose in Chinese patients with gastrointestinal tumor undergoing surgery: A multicenter, randomized, non-inferiority trial

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Supplementary Table 1. Table of approximate composition of study products (per 100 kcal)

Nutrient	TPF-T	FSMP
Energy, kcal	100	100
Protein, g	4.5	6.8
Fat, g	5.5	3.4
Carbohydrate, g	8.0	9.7
Fiber, g	1	1.6
Vitamins		
A, µg RE	154	83.2
D, µg	0.4	1.4
E, mgα-TE	2.1	4.7
K, µg	5.1	8.0
C, mg	6.2	34.4
Thiamin, mg	0.1	0.2
Riboflavin, mg	0.1	0.2
B_6, mg	0.1	0.2
B_{12}, µg	0.2	0.4
Pantothenic acid, mg	0.4	0.8
Folic acid, µg	10.0	28.6
Niacin, mg	0.9	0.96
Biotin, µg	10.0	4.0
Choline, mg	20.5	40.8
Minerals		
Sodium, mg	61.5	106
Potassium, mg	132.3	143.9
Chloride, mg	95.4	128.5
Calcium, mg	38.5	93.3
Phosphorus, mg	38.5	53.2
Magnesium, mg	16.9	33.5
Iron, mg	1.0	1.1
Zinc, mg	0.8	1.7
Copper, µg	100.0	61.9
Manganese, mg	0.2	0.3
Iodine, µg	10.2	12.8
Selenium, µg	5.2	6.3
Chromium, µg	5.1	6.4
Molybdenum, µg	7.7	8.8
Floride, mg	0.1	0
Others		
ω-3 Fatty acid[†], g	0.2	0.5
Added Glutamine, g	0	0.75
Taurine, mg	0	11.0
L-Carnitine, mg	0	8.0

[†]including EPA and DHA

Supplementary Table 2. Comparison of analysis for the primary outcome in the full analysis set with and without multiple imputation

	Visit	Group	n	Least square means (SE)	95%CI	Least square means differences (FSMP - TPF-T)		
						Least square means (SE)	95%CI	*p* value
With multiple imputation	Change from baseline to final visit/ Exit	FSMP (N=162)	162	-57.7 (11.3)	-79.8, -35.6	7.9 (5.5)	-2.9, 18.7	0.152
		TPF-T (N=163)	163	-65.6 (11.1)	-87.4, -43.9			
Without multiple imputation	Change from baseline to final visit/ Exit	FSMP (N=162)	151	-57.5 (11.3)	-79.8, -35.3	7.3 (5.50)	-3.5, 18.2	0.184
		TPF-T (N=163)	154	-64.9 (11.1)	-86.7, -43.0			

SE: Standard Error; CI: confidence interval
Least square means and confidence intervals were from an ANCOVA model containing treatment group, study site and randomization stratification as factors and baseline result as a covariate.

Supplementary Table 3. Subgroup analysis of serum pre-albumin levels

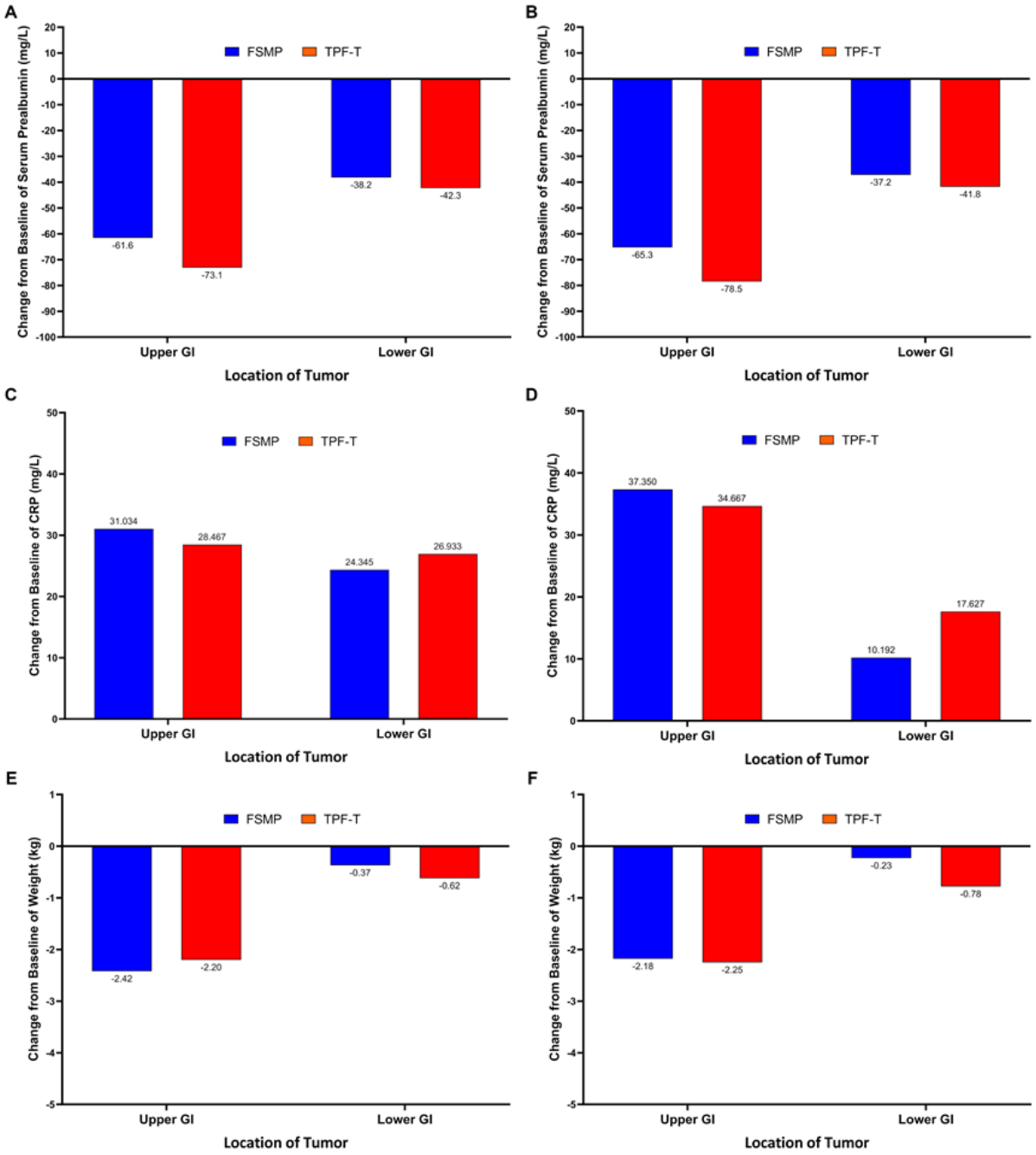
Outcomes	FAS				PPS			
	FSMP group	Control group	95%CI	*p* value	FSMP group	Control group	95%CI	*p* value
9±3 days post-surgery								
Upper gastrointestinal tumor			-9.3, 32.2	0.275			-8.6, 35.0	0.230
n	53	56			31	35		
Change from baseline, mg/L, LS mean (SE)	-61.6 (17.2)	-73.1 (16.6)			-65.3 (15.5)	-78.5 (14.9)		
Difference between groups, mg/L, LS mean (SE)	11.5 (10.5)				13.2 (10.9)			
Lower gastrointestinal tumor			-8.5, 16.6	0.524			-9.9, 19.1	0.530
n	98	98			69	65		
Change from baseline, mg/L, LS mean (SE)	-38.2 (23.4)	-42.3 (23.0)			-37.2 (22.9)	-41.8 (22.4)		
Difference between groups, mg/L, LS mean (SE)	4.1 (6.37)				4.6 (7.32)			
Laparoscopy			-4.0, 18.0	0.212			-4.9, 19.2	0.245
n	149	150			99	96		
Change from baseline, mg/L, LS mean (SE)	-65.8 (5.47)	-72.8 (5.54)			-62.6 (7.20)	-69.8 (7.10)		
Difference between groups, mg/L, LS mean (SE)	7.0 (5.58)				7.1 (6.12)			
1 day before surgery/Surgery day								
Upper gastrointestinal tumor			-0.1, 18.8	0.053			-8.0, 16.4	0.493
n	51	57			31	35		
Change from baseline, mg/L, LS mean (SE)	17.9 (7.88)	8.6 (7.48)			19.9 (8.71)	15.7 (8.36)		
Difference between groups, mg/L, LS mean (SE)	9.3 (4.77)				4.2 (6.11)			
Lower gastrointestinal tumor			-11.1, 4.4	0.396			-13.4, 5.3	0.394
n	96	91			68	64		
Change from baseline, mg/L, LS mean (SE)	-8.2 (14.1)	-4.8 (13.9)			-8.2 (15.0)	-4.1 (14.6)		
Difference between groups, mg/L, LS mean (SE)	-3.4 (3.94)				-4.0 (4.73)			
Laparoscopy			-5.2, 7.0	0.771			-9.1, 5.9	0.671
n	145	144			98	95		
Change from baseline, mg/L, LS mean (SE)	11.9 (3.15)	11.0 (3.19)			12.0 (5.22)	13.6 (5.04)		
Difference between groups, mg/L, LS mean (SE)	0.9 (3.09)				-1.6 (3.78)			

FAS: full analysis set; PPS: per protocol set; LS: least squares; SE: standard error; CI: confidence interval.

Supplementary Table 3. Subgroup analysis of serum pre-albumin levels (cont.)

Outcomes	FAS				PPS			
	FSMP group	Control group	95%CI	*p* value	FSMP group	Control group	95%CI	*p* value
1 day post-surgery								
Upper gastrointestinal tumor			-1.5, 19.0	0.095			-5.2, 20.5	0.237
n	50	55			31	34		
Change from baseline, mg/L, LS mean (SE)	-37.0 (8.46)	-45.8 (8.02)			-37.7 (9.11)	-45.4 (8.80)		
Difference between groups, mg/L, LS mean (SE)	8.7 (5.17)				7.7 (6.42)			
Lower gastrointestinal tumor			-6.6, 7.8	0.862			-7.7, 8.2	0.950
n	93	87			67	64		
Change from baseline, mg/L, LS mean (SE)	-40.8 (12.8)	-41.5 (12.6)			-38.3 (12.8)	-38.6 (12.4)		
Difference between groups, mg/L, LS mean (SE)	0.6 (3.65)				0.3 (4.04)			
Laparoscopy			-2.7, 9.1	0.287			-4.3, 9.3	0.467
n	141	138			97	94		
Change from baseline, mg/L, LS mean (SE)	-41.8 (2.90)	-45.0 (2.99)			-39.2 (4.75)	-41.7 (4.63)		
Difference between groups, mg/L, LS mean (SE)	3.2 (3.00)				2.5 (3.44)			

FAS: full analysis set; PPS: per protocol set; LS: least squares; SE: standard error; CI: confidence interval.



Supplementary Figure 1. Subgroup analysis of change from baseline in serum pre-albumin levels, CRP and body weight at 9±3 days post-surgery. (A) pre-albumin levels in FAS, (B) pre-albumin levels in PPS, (C) CRP in FAS, (D) CRP in PPS, (E) body weight in FAS, (F) body weight in PPS.