[Fig. 1]

Proportion of responder (n of responder/n of cases)	Placebo	EPA-E 1800mg/day
All Cases	32.7% (18/55)	32.7% (18/55)
Non-Diabetes	27.5% (11/40)	41.9% (13/31)
Non-Diabetes + Mild Diabetes (anti-diabetes agent ≦1)	27.7% (13/47)	37.8% (17/45)

p value by χ square test vs. Placebo	EPA-E 1800mg/day
All Cases	1.000
Non-Diabetes	0.202
Non-Diabetes + Mild Diabetes (anti-diabetes agent ≦1)	0.301

Fig. 1

[Fig. 2]

Proportion of responder (n of responder/n of cases)		Placebo	EPA-E 1800mg/day
All Cases	HbA1c=<6.4	23.7% (9/38)	42.1%* (16/38)
Non-Diabetes	HbA1c=<6.4	22.9% (8/35)	46.4%** (13/28)

χ square test vs.Placebo

*: p<0.10 **: p<0.05

p value by χ square test vs. Placebo		EPA-E 1800mg/day
All Cases	HbA1c=<6.4	0.087*
Non-Diabetes	HbA1c=<6.4	0.049**

Fig. 2

[Fig. 3]

Proportion of responder (n of responder/n of cases)		Placebo	EPA-E 1800mg/day
All Cases	Glucose=<125	25.6% (11/43)	36.2% (17/47)
Diabetes	Glucose=<125	0.0% (0/5)	22.2% (4/18)
Non-Diabetes	Glucose=<125	28.9% (11/38)	44.8% (13/29)

p value by χ square test vs. Placebo		EPA-E 1800mg/day
All Cases	Glucose=<125	0.278
Diabetes	Glucose=<125	0.246
Non-Diabetes	Glucose=<125	0.179

Fig. 3

[Fig. 4]

Proportion of responder (n of responder/n of cases)		Placebo	EPA-E 1800mg/day
All Cases	HbA1c=<6.4 and Glucose=<125	22.9% (8/35)	43.2%* (16/37)
Diabetes	HbA1c=<6.4 and Glucose=<125	0.0% (0/2)	33.3% (3/9)
Non-Diabetes	HbA1c=<6.4 and Glucose=<125	24.2% (8/33)	46.4%* (13/28)

χ square test vs.Placebo

*: p<0.10

p value by χ square test vs. Placebo		EPA-E 1800mg/day
All Cases	HbA1c=<6.4 and Glucose=<125	0.067*
Diabetes	HbA1c=<6.4 and Glucose=<125	0.338
Non-Diabetes	HbA1c=<6.4 and Glucose=<125	0.069*

Fig. 4

[Fig. 5-1]

	Pre-treatment baseline		After dosing (effect) values	
Item (Typical Normal Values, Units)	Typical Range(s)	Observable Ranges or Values	Typical Range(s)	Observable Ranges or Values
ALT (6-41 U/L)	10-300	Lower limit range values of 10, 50, 100, 150, or 200, upper limit range values of 100, 150, 200, 250, or 300, ranges of 10-300, 10-200, 10-150, 10-100, 100-200, 2000-3000	at least 1% lower	1 to about 95% reduction
AST (9-34 U/L)	10-250	Lower limit range values of 10, 50, 100, 150, or 200, upper limit range values of 100, 150, 200, 250, or 300, ranges of 10-300, 10-200, 10-150, 10-100, 100-200, 200-300	at least 1% lower	1 to about 95% reduction
AST/ALT ratio		upper limit range values of 0.5, 0.7, 0.8, 1, 1.2, 2; ranges of 0.5-2, 0.5-1-1-2		
alkaline phospatase (ALP) (80-260 IU/L)	80-300	ranges of 50-600	no worsening	no worsening, 1 to about 90% reduction, 300 IU/L or less, 250 IU/L or less
Total bilirubin (0.2-1.2 mg/dL)			no worsening	no worsening, 1 to about 90% reduction
Gamma-Glutamyl Transferase (GGT or γGTP) (males: 5-60 U/L)			no worsening	no worsening, 1 to about 90% reduction, 100 U/L or less, 70 U/L or less
Albumin (3.8-5.2 g/dl)			no worsening	no worsening, 1 to about 90% increase, ranges of 3-6 g/dl, 3.5-5.5 g/dl
HDL-C (high density lipoprotein cholesterol) (35-60- mg/dl)	less than 55	less than 60 mg/dl, 55, 50, 45, 40, 35, 30, 25, or 25 mg/dl; ranges of 25-55, 30-40 mg/dl, 40-50 mg/dl, 50-60 mg/dl, at least 60	no worsening, at least 1% increase	no change, 1-90% increase, 40 mg/dl or more
LDL-C (low density lipoprotein cholesterol) (50-130 mg/dl)	100-200	at least 70 mg/dl, 100, 120, 130 140 150, 170, 190, or 200 or a range of 70-300, 70-250, 70-200, 100-250, 100-200, 130-200, 140-180, 100-130, 130-160, 160-190	no worsening	no change, 1-90% reduction less than 160 mg/dl, 140, 130, 120, 100, 70 mg/dl

Fig. 5

[Fig. 5-2]

	Pre-treatment baseline		After dosing (effect) values	
Item (Typical Normal Values, Units)	Typical Range(s)	Observable Ranges or Values	Typical Range(s)	Observable Ranges or Values
Triglycerides (TG) (fed or fasting, 50-150 mg/dl)	100-1000	at least 80 mg/dl, 100, 150, 180, 200, 300, 500, 700, 1000, 1200, or 1500, or less than 150, or a range of 100-2500, 100-1500, 100-1000, 150-500, 200-500, 150-300, 150-200, 200-500	at least 1% lower	1 to about 90% reduction, 500 mg/dl or less, 300, 200, 150, 100 mg/dl or less
Total Cholesterol (TC) (100-200 mg/dl)	170-300	a range of 130-300 mg/dl, 200-220, 220-240, 240-260, or at least 260, or less than 200 mg/dl	no worsening	no change, 1-90% reduction
TG and HDL-C	High TG and low HDL-C (ex. TG ≧ 150 mg/dl and HDL ≦ 40 mg/dl	TG: at least 150, 200, 500 mg/dl HDL-C; less than 40, 50 mg/dl	no worsening	
TG/HDL-C ratio	at least 3.75	at least 2, 2.5, 3, 3.75, 4, 5, 10, or ranges of 2-3.75, 3.75-10	at least 1% lower	no worsening, at least 1% lower, or 1-90% reduction
Non-HDL-C (mg/dl)	at least 130	at least 100 mg/dl, 130, 150, 160, 170, 190, a range of 100 to 250	no worsening	no worsening, or at least 1% lower, or less than 130 mg/dl, 150, 160, 170, 190
Free fatty acid (μ Eq/l) (140-850)	at least 400	less than 400, at least 400, 600, 800, 1000	at least 1% lower	no change, or at least 1 to 90% reduction
Eicosapentaenoic Acid/Arachidonic Acid (EPA/AA) (ex. (mol/%)/(mol/%)	less than 0.5/low compared to average level or normal subjects	less than 1, 0.75, 0.5, 0.1, ranges of 0.01-2	at least 5% increase	5 to about 200% increase, about 2-200-fold increase
Arachidonic Acid (AA) (ex. mol/%)	High compared to average level of normal subjects		at least 1% lower	no change, 1 to about 90% reduction
Eicosapentaenoic Acid (EPA) (ex. mol/%)	low compared to average level of normal subjects		at least 5% increase	5 to about 200% increase, about 2-500-fold increase
Docosapentaenoic Acid (DPA) (ex. mol/%)	low compared to average level of normal subjects		at least 1% increase	1 to about 95% increase
Docosahexaenoic Acid (DHA) (ex. mol/%)	low compared to average level of normal subjects			
DPA/AA ratio	low compared to average level of normal subjects			

Fig. 5 (continued)

[Fig. 5-3]

	Pre-treatment baseline		After dosing (effect) values	
Item (Typical Normal Values, Units)	Typical Range(s)	Observable Ranges or Values	Typical Range(s)	Observable Ranges or Values
DPA/AA ratio	low compared to average level of normal subjects			
DHA/DPA ratio	low compared to average level of normal subjects			
Monounsaturated fatty acid (MUFA) (ex. mol/%)	High compared to average level of normal subjects		at least 1% lower	no change, at least 1% lower
Palmitoleic acid (16:1 n7) (ex. mol/%)	High compared to average level of normal subjects		at least 1% lower	no change, at least 1% lower
Oleic acid (18:1 n9) (ex. mol/%)	High compared to average level of normal subjects		at least 1% lower	no change, a least 1% lower
Oleic acid (18:1 n9)/ stearic acid (18:0) ratio	High compared to average level of normal subjects		at least 1% lower	no change, at least 1% lower
Palmitoleic acid (16:1)/ Palmitic acid (16:0) ratio	High compared to average level of normal subjects		at least 1% lower	no change, at least 1% lower
Stearic acid (18:0)/ Palmitic acid (16:0) ratio	High compared to average level or normal subjects		no change, or at least 1% lower	no change, or at least 1% lower
γ-linoleic acid(18:3 n6)/ Linoleic acid (18:2 n6) ratio	High compared to average level subjects		no change, or at least 1% lower	no change, or at least 1% lower
AA/Homo-γ-linolenic acid (20:3 n6) ratio	low compared to average level of normal subjects		no change, or at least 1% Increase	no change, or at least 1% increase
Acrenic acid (22:4 n6)/ AA ratio	High compared to average level of normal subjects		no change, or at least 1% lower	no change, or at least 1% lower
Ferritin (ng/mL)		at least 100, 120, 150, 200, 250, 300, 350, 400, or 500	at least 1% lower	at least 1 to about 95% lower
Thioredoxin (ng/mL)		at least 15, 20, 25, 30, 35, 40, 45, or 50	at least 1% lower	at least 1 to about 95% lower
TNFα (pg/mL) (1.79 or less)	at least 1.5	at least 1, 1.5, 1.6, 1.7, 1.79, 1.8, 1.9, 2.0, 2.2, 2.5, 3, 3.5, 4, 5, 6, 7 or 10	at least 1% lower	at least 1 to about 95% lower

Fig. 5 (continued)

[Fig. 5-4]

	Pre-treatment baseline		After dosing (effect) values	
Item (Typical Normal Values, Units)	Typical Range(s)	Observable Ranges or Values	Typical Range(s)	Observable Ranges or Values
sTNF-R1 (pg/mL)		at least 400, 500, 600, 700, 800, 900, 1000, 1100, 1200, 1500, or 2000	at least 1% lower	at least 1 to about 95% lower
sTNF-R2 (pg/mL)		at least 500, 700, 1000, 1200, 1500, 1700, 2000, 2200, 2500, 2700, or 3000	at least 1% lower	at least 1 to about 95% lower
High Sensitivity C-reactive protien (Hs-CRP, mg/dl)	0.2	0.1 or more, 0.2, 0.3, 0.4, 0.5 or more, ranges of 0.1-1, 0.1-0.8, 0.1-0.5, 0.2-0.5	at least 1% lower	at least 5 to about 95% lower
Connective Tissue Growth Factor (CTGF)			at least 1% lower	at least 5 to about 95% lower
Serum Soluble CD40 (sCD40, pg/ml)		5 pg/ml or more, 10, 20, 30, 50, 70, 100, 120, 150, 170, 200, 220, 250, 300, 350, 400, 450, 500 or more	at least 1% lower	at least 5 to about 95% lower
Insulin resistance Index (HOMA-IR) (1.6 or less)	1.5 or more	1.6 or less/1.5 or more, 1.6, 2, 2.5, 3, 3.5, 4	no worsening	no change, at least 1 to about 50% lower
Glycated hemoglobin (HbA1c) (4.3-5.8%)	5.7 or more	a range of 4.3-5.8, 5.7-6.4, 5.8-6.5, 6.5-7.0, 7.0-8.0/5.7 or more, 5.8, 6, 6.5, 7, 7.5, 8, or 8.5	no worsening	no change, at least 1 to about 50% lower
Fasting plasma glucose (FPG) (mg/dl) (less than 100)	100 or more	less than 100/ 100 or more, 110, 120, 126, 130, 150, 200, 250, 300/ ranges of 100-110, 100-126	no worsening	no change, or at least 1 to about 50% lower
Postprandial plasma glucose (after a meal)	140 or more	less than 140, 160, 200/ 140 or more, 170, 180, 200, 250, 300, 350 400/ranges of 140-200, 140-170, 170-200	no worsening	no change, or at least 1 to about 50% lower
two-hour glucose levels on the 75-g oral glucose tolerance test (mg/dl) (OGTT)	140-200	less than 140, 160, 200/140 or more, 170, 180, 200, 250, 300, 350, 400/ ranges of 140-200, 140-170, 170-200	no worsening	no change, or at least 1 to about 50% lower
Leptin (ng/ml)		5 ng/ml or more, 10, 12, 15, 17, 20, 22, 25, 30, 35, 40 or more	at least 1% lower	at least 1 to about 95% reduction

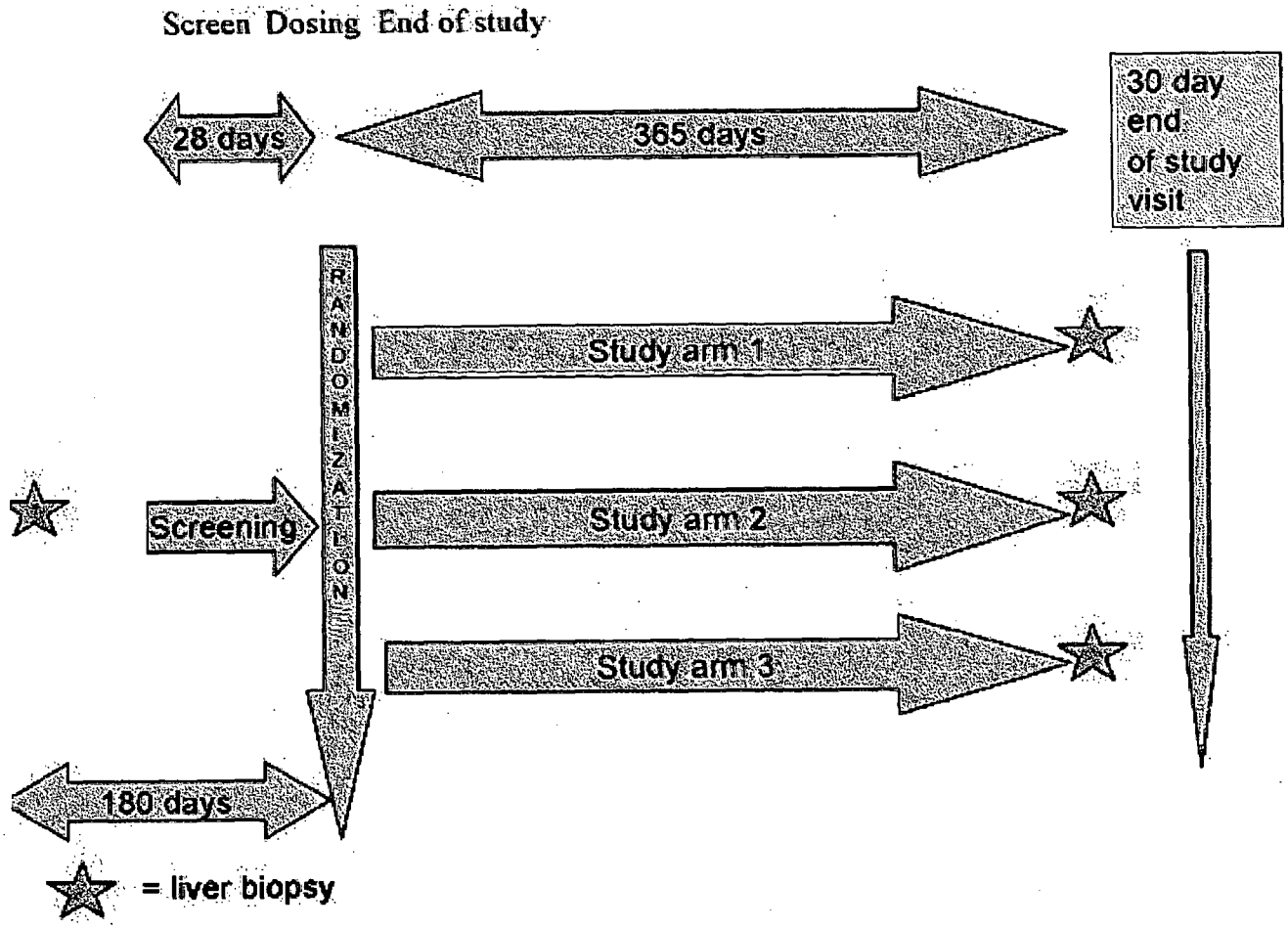
Fig. 5 (continued)

[Fig. 5-5]

	Pre-treatment baseline		After dosing (effect) values	
Item (Typical Normal Values, Units)	Typical Range(s)	Observable Ranges or Values	Typical Range(s)	Observable Ranges or Values
Serum adiponectin (μg/mL)		5 μg/mL or less, 4.5, 4, 3.5, or 3 μg/mL or less	at least 1% increase	no change, at least 1 to about 95% increase
complement factor D			at least 15% lower	at least 1 to about 95% reduction
CK18 fragment			at least 1% lower	at least 1 to about 95% reduction
serum High mobility group box 1 protein (HMGB1)			at least 1% lower	at least 1 to about 95% reduction
Fas			at least 1% lower	at least 1 to about 95% reduction
Hyaluronic acid (50 ng/mL or less)		25 ng/mL or more, 50, 70, 100, 120, 150, 200, 250, or 300 or more; 200 mL or less, 100, 70, or 50 or less	at least 1% lower	at least 1 to about 95% reduction
Type IV collagen (7s domain) (6 ng/mL or less)		5 ng/mL or more, 6, 7, 8, 10, 12, 15, or 20 or more; 25 ng/mL or less, 20, 15, 10, or 6 or less	at least 1% lower	at least 1 to about 95% reduction
procollagen III peptide 0.3-0.8 U/ml		0.2 U/ml or more, 0.3, 0.5, 0.7, 1, 1.2, 1.5, 2, 2.5, 3, 3.5, or 4 or more; 10 or less, 8, 5, 3, 1, or 0.8 or less	at least 1% lower	at least 1 to about 95% reduction
PAI-1 (ng/mL) 50 or less	50 or more			
		Items other than serum		
platelet count 150000-400000/μl	150000-300000	400000/μl or less, 300000, 200000/a range of 150000-300000	no change	no change, at least 1% increase
BMI	18.5-40	18.5 or more, 20, 25, 30, 35, 40, or 50 or more;/50 or less, 40, 30, 25, 20 or 18.5 or less; or range of 18.5-25, 25-30, 30-35, 35-40	no change	no change, at least 1% reduction

Fig. 5 (continued)

[Fig. 6]



Note: PK sampling will be undertaken in 12 subjects per arm (6 male, 6 female)

Fig. 6

[Fig. 7]

Proportion of responder (n of responder/n of cases)	All Cases	Placebo	EPA-E 1800mg/day	EPA-E 2700mg/day
All Cases	32.2% (56/174)	32.7% (18/55)	32.7% (18/55)	31.3% (20/64)
GGT≦33	41.9% (13/31)	23.1% (3/13)	45.5% (5/11)	71.4%* (5/7)
GGT>33	30.1% (43/143)	35.7% (15/42)	29.5% (13/44)	26.3% (15/57)

χ square test vs Placebo * : $p<0.05$

p value by χ square test vs. Placebo	All Cases	Placebo	EPA-E 1800mg/day	EPA-E 2700mg/day
All Cases	-	-	1.000	0.863
GGT≦33	-	-	0.247	0.035*
GGT>33	-	-	0.542	0.315

Fig. 7

[Fig. 8-1]

Primary endpoint achieved rate (n of achieved/n of cases)	Placebo	EPA-E 1800mg/day	EPA-E 2700mg/day
GGT=<24,25,26 or 27	12.5% (1/8)	50.0% (2/4)	60.0%* (3/5)
GGT=<28	12.5% (1/8)	40.0% (2/5)	60.0%* (3/5)
GGT=<29	12.5% (1/8)	33.3% (2/6)	66.7%** (4/6)
GGT=<30	11.1% (1/9)	33.3% (2/6)	66.7%** (4/6)
GGT=<31	10.0% (1/10)	28.6% (2/7)	66.7%** (4/6)
GGT=<32	16.7% (2/12)	33.3% (3/9)	66.7%** (4/6)
GGT=<33	23.1% (3/13)	45.5% (5/11)	71.4%** (5/7)
GGT=<34	23.1% (3/13)	41.7% (5/12)	62.5%* (5/8)
GGT=<35	23.1% (3/13)	41.7% (5/12)	55.5% (5/9)
GGT=<40	27.8% (5/18)	38.9% (7/18)	46.7% (7/15)
GGT=<45	27.8% (5/18)	40.9% (9/22)	33.3% (8/24)
GGT=<50	28.6% (6/21)	38.5% (10/26)	32.1% (9/28)
GGT=<55	30.4% (7/23)	35.5% (11/31)	31.3% (10/32)
GGT=<60	28.0% (7/25)	36.4% (12/33)	31.3% (10/32)
GGT male=<30, female=<24	11.1% (1/9)	33.3% (2/6)	60.0%* (3/5)

Fig. 8

[Fig. 8-2]

χ square test vs.Placebo * p<0.10 ** p<0.05

p value by χ square test vs. Placebo	Placebo	EPA-E 1800mg/day	EPA-E 2700mg/day
GGT=<24,25,26 or 27	-	0.157	0.071*
GGT=<28	-	0.252	0.071*
GGT=<29	-	0.347	0.036**
GGT=<30	-	0.292	0.025**
GGT=<31	-	0.323	0.018**
GGT=<32	-	0.375	0.034**
GGT=<33	-	0.247	0.035**
GGT=<34	-	0.319	0.071*
GGT=<35	-	0.319	0.119
GGT=<40	-	0.480	0.261
GGT=<45	-	0.386	0.700
GGT=<50	-	0.477	0.788
GGT=<55	-	0.697	0.949
GGT=<60	-	0.502	0.790
GGT male=<30, female=<24	-	0.292	0.052*

Fig. 8 (continued)

[Fig. 9]

Change of NAS score mean±SD (n)	Placebo	EPA-E 1800mg/day	EPA-E 2700mg/day
All Cases	0.927±1.500 (55)	1.018±1.258 (55)	0.844±1.573 (64)
GGT≦33	0.769±1.527 (13)	1.818±1.029* (11)	2.286±1.248* (7)
GGT>33	0.976±1.476 (42)	0.818±1.230 (44)	0.667±1.514 (57)

Student's t test vs Placebo * $p<0.05$

p value by student's t test vs. Placebo	Placebo	EPA-E 1800mg/day	EPA-E 2700mg/day
All Cases	-	0.367	0.385
GGT≦33	-	0.039*	0.024*
GGT>33	-	0.298	0.159

Fig. 9

[Fig. 10]

EPA/AA ratio at Day365 mean±SD (n)	Placebo	EPA-E 1800mg/day	EPA-E 2700mg/day
All Cases	0.076±0.080 (46)	0.311±0.206 (51)	0.557±0.374 (56)
GGT≦33	0.124±0.165 (8)	0.313±0.192 (11)	1.026±0.488* (7)
GGT>33	0.077±0.080 (38)	0.383±0.251 (40)	0.507±0.326 (49)

Student's t test vs GGT>33 * p<0.05

p value by student's t test	Placebo	EPA-E 1800mg/day	EPA-E 2700mg/day
GGT≦33 vs GGT>33	0.070	0.202	0.0004*

Fig. 10

[Fig. 11-1]

Parameter (Baseline)	Group	GGT=<33	GGT>33	Stedman [a]	Merck Manual [b]
GGT (U/L)	Placebo	24.4±6.4	102.9±71.5	M:2-30 F:1-24	8-78
	1800	27.8±4.7	98.0±125.2		
	2700	23.3±6.4	95.4±111.9		
ALP (U/L)	Placebo	62.8±13.1	93.7±38.9	-	36-92
	1800	71.1±17.0	82.1±24.9		
	2700	76.3±20.8	90.1±25.9		
Direct Bilirubin (mg/dL)	Placebo	0.09±0.03	0.11±0.05	0-0.4	0-0.3
	1800	0.11±0.03	0.10±0.05		
	2700	0.11±0.05	0.11±0.05		
ALT (U/L)	Placebo	47.4±22.9	96.0±48.9	M:13-40 F:10-28	0-35
	1800	51.5±28.4	94.0±51.9		
	2700	86.4±79.2	81.6±34.8		

Fig. 11

a) Stedmansonline Laboratory Reference Range Values
b) Merck Manual Appendix II Normal Laboratory Values

[Fig. 11-2]

Parameter (Baseline)	Group	GGT=<33	GGT>33	Stedman [a)]	Merck Manual [b)]
AST (U/L)	Placebo	35.0±12.9	69.3±44.2	10-59	0-35
	1800	36.1±16.1	68.6±38.9		
	2700	66.7±63.7	61.1±32.4		
Albumin(g/dL)	Placebo	4.52±0.38	4.53±0.62	3.5-5.2 (>60y 3.2-4.6)	3.5-5.5
	1800	4.47±0.29	4.56±0.27		
	2700	4.66±0.18	4.53±0.29		
Ferritin (ng/mL)	Placebo	76.0±51.6	253.3±221.4	M 20-150 F 10-120	15-200
	1800	134.7±96.1	239.6±264.1		
	2700	151.3±98.5	234.9±159.4		
CK18 Fragment (U/L)	Placebo	428.5±229.1	928.5±839.5	-	
	1800	357.7±174.4	811.5±665.7		
	2700	546.7±368.4	798.0±673.5		

Fig. 11 (continued)

[Fig. 12]

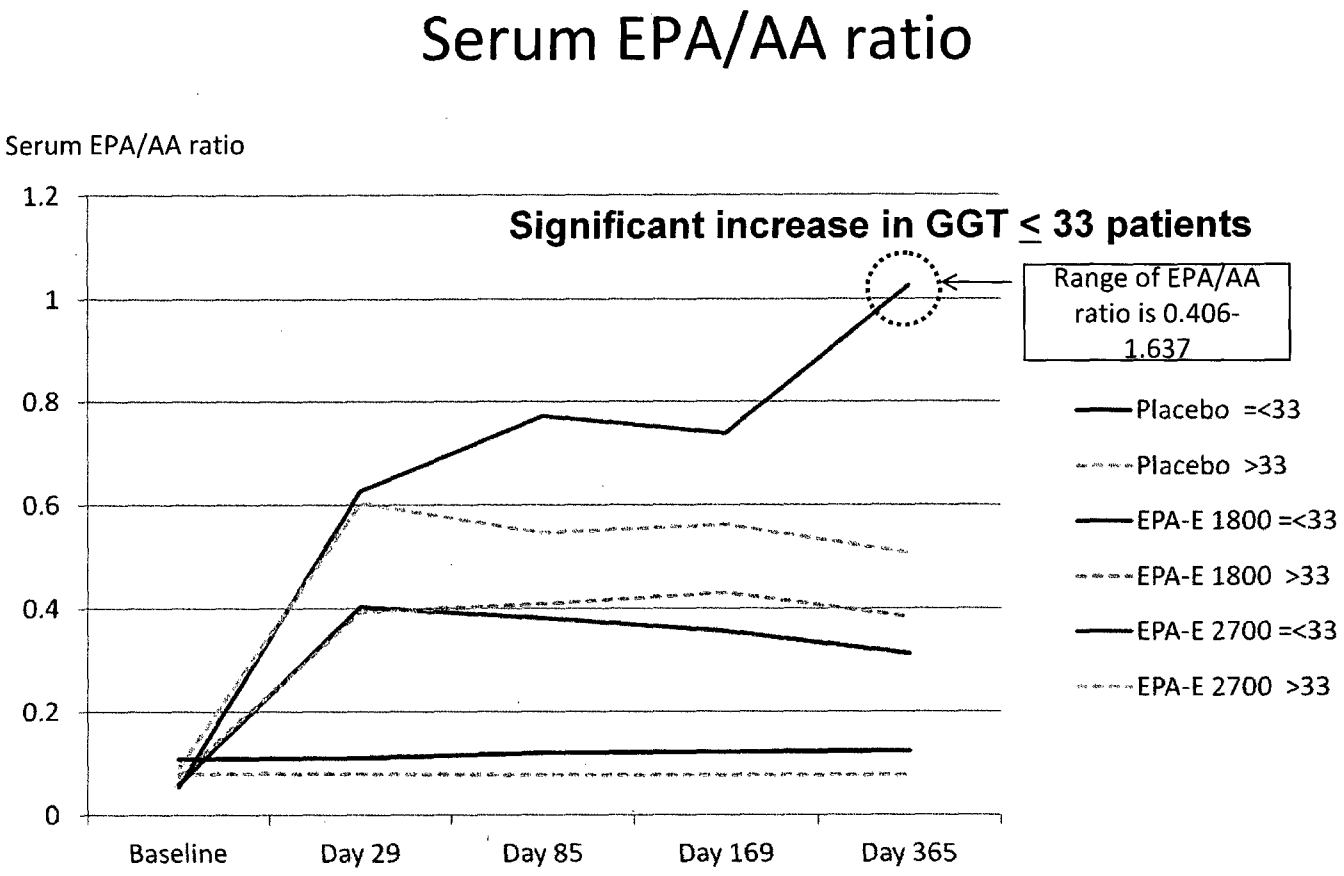

Serum EPA/AA ratio
Serum EPA/AA ratio
Significant increase in GGT ≤ 33 patients
Range of EPA/AA ratio is 0.406-1.637
1.2
1
0.8
0.6
0.4
0.2
0
Baseline
Day 29
Day 85
Day 169
Day 365
Placebo =<33
Placebo >33
EPA-E 1800 =<33
EPA-E 1800 >33
EPA-E 2700 =<33
EPA-E 2700 >33

Fig. 12

[Fig. 13]

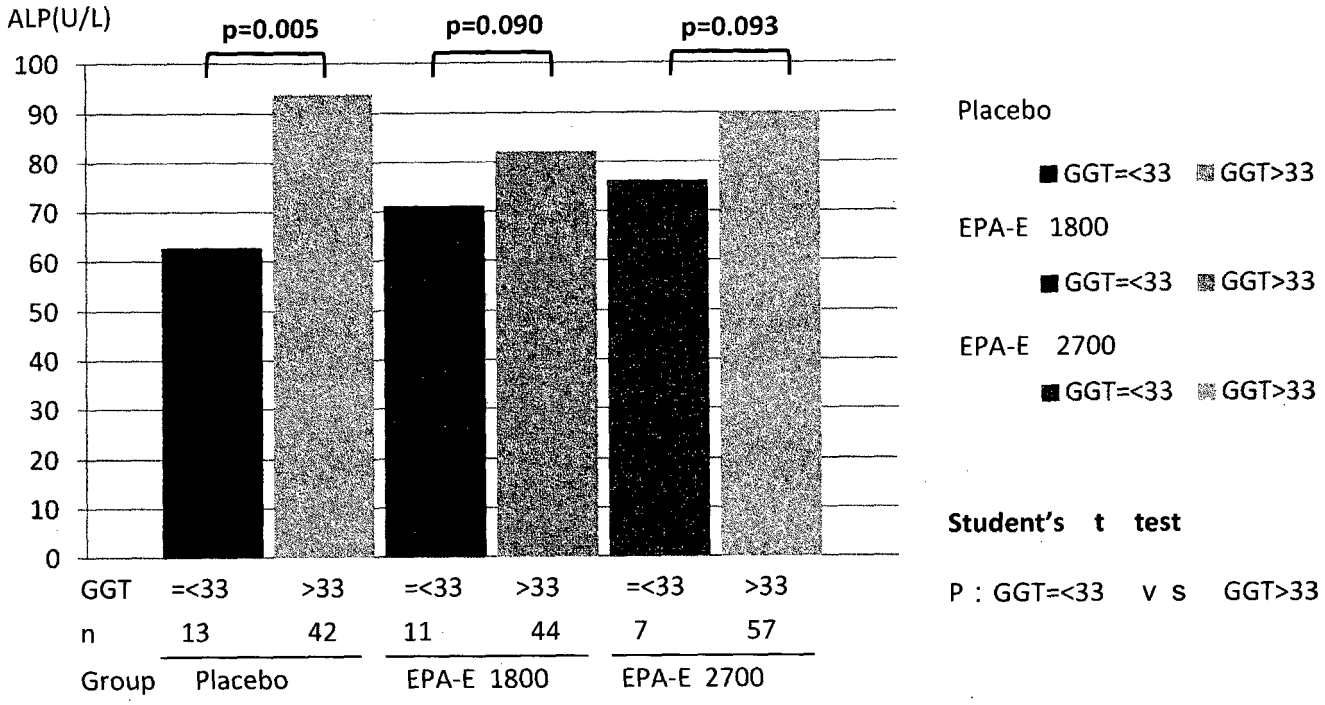

ALP(U/L)
p=0.005
p=0.090
p=0.093
100
90
80
70
60
50
40
30
20
10
0
GGT =<33 >33 =<33 >33 =<33 >33
n 13 42 11 44 7 57
Group Placebo EPA-E 1800 EPA-E 2700
Placebo
GGT=<33 GGT>33
EPA-E 1800
GGT=<33 GGT>33
EPA-E 2700
GGT=<33 GGT>33
Student's t test
P : GGT=<33 v s GGT>33

Fig. 13

[Fig. 14]

Proportion of responder (n of responder/n of cases)	Placebo	EPA-E 1800mg/day
All Cases	32.7% (18/55)	34.0% (18/53)
sFas≦9.5	33.3% (3/9)	80.0%** (8/10)
sFas>9.5	32.6% (15/46)	23.3 (10/43)

χ square test vs Placebo

** p<0.05

p value by χ square test vs. Placebo	Placebo	EPA-E 1800mg/day
All Cases	-	0.892
sFas≦9.5	-	0.040**
sFas>9.5	-	0.327

Fig. 14

[Fig. 15-1]

χ square test vs Placebo * p<0.10 ** p<0.05

Proportion of responder (n of responder/n of cases)	Placebo	EPA-E 1800mg/day
sFas=<10.0	36.4% (4/11)	61.5% (8/13)
sFas=<9.9	36.4% (4/11)	61.5% (8/13)
sFas=<9.8	40.0% (4/10)	61.5% (8/13)
sFas=<9.7	40.0% (4/10)	72.7% (8/11)
sFas=<9.6	40.0% (4/10)	72.7% (8/11)
sFas=<9.5	33.3% (3/9)	80.0%** (8/10)
sFas=<9.4	37.5% (3/8)	88.9%** (8/9)
sFas=<9.3	37.5% (3/8)	87.5%** (7/8)
sFas=<9.2	42.9% (3/7)	100.0%** (5/5)
sFas=<9.1	50.0% (3/6)	100.0%* (5/5)
sFas=<9.0	50.0% (3/6)	100.0%* (5/5)
sFas=<8.9	50.0% (3/6)	100.0%* (4/4)
sFas=<8.8	50.0% (3/6)	100.0%* (4/4)
sFas=<8.7	50.0% (3/6)	100.0% (3/3)

Fig. 15

[Fig. 15-2]

χ square test vs.Placebo *:p<0.10 **:p<0.05

p value by χ square test vs. Placebo	Placebo	EPA-E 1800mg/day
sFas=<10.0	-	0.219
sFas=<9.9	-	0.219
sFas=<9.8	-	0.305
sFas=<9.7	-	0.130
sFas=<9.6	-	0.130
sFas=<9.5	-	0.040**
sFas=<9.4	-	0.027**
sFas=<9.3	-	0.039**
sFas=<9.2	-	0.038**
sFas=<9.1	-	0.064*
sFas=<9.0	-	0.064*
sFas=<8.9	-	0.091*
sFas=<8.8	-	0.091*
sFas=<8.7	-	0.134

Fig. 15 continued

[Fig. 16]

Change of NAS score mean±SD (n)	Placebo	EPA-E 1800mg/day
All Cases	0.927±1.500 (55)	1.057±1.265 (53)
sFas≦9.5	1.000±1.491 (9)	2.200±0.872** (10)
sFas>9.5	0.913±1.501 (46)	0.791±1.192 (43)

Student's t test vs Placebo **:p<0.05

p value by student's t test vs. Placebo	Placebo	EPA-E 1800mg/day
All Cases	-	0.316
sFas≦9.5	-	0.028**
sFas>9.5	-	0.338

Fig. 16

[Fig. 17]

Proportion of responder (n of responder/n of cases)	Placebo	EPA-E 1800mg/day
M30=<1500	26.7% (12/45)	31.9% (15/47)
M30=<1000	26.7% (12/45)	34.9% (15/43)
M30=<900	21.4% (9/42)	34.9% (15/43)
M30=<800	23.7% (9/38)	33.3% (14/42)
M30=<700	25.0% (9/36)	32.4% (12/37)
M30=<600	26.6% (8/30)	35.5% (11/31)
M30=<500	25.9% (7/27)	45.5% (10/22)

p value by χ square test vs. Placebo	Placebo	EPA-E 1800mg/day
M30=<1500	-	0.581
M30=<1000	-	0.403
M30=<900	-	0.168
M30=<800	-	0.341
M30=<700	-	0.483
M30=<600	-	0.433
M30=<500	-	0.153

Fig. 17

[Fig. 18-1]

Student's t test vs Placebo *:p<0.10 **:p<0.05

Proportion of responder (n of responder/n of cases)		Placebo	EPA-E 1800mg/day	EPA-E 2700mg/day
sFas=<10.0	M30≦1500	27.3 (3/11)	58.3 % (7/12)	47.1 % (8/17)
	M30≦600	30.0% (3/10)	66.6 % (6/9)	50.0 % (6/12)
	M30≦500	25.0% (2/8)	66.6 %* (6/9)	55.5 % (5/9)
sFas=<9.7	M30≦1500	33.3% (3/9)	70.0 % (7/10)	61.5% (8/13)
	M30≦600	37.5% (3/8)	66.6 % (6/9)	75.0 % (6/8)
	M30≦500	33.3% (2/6)	66.6 % (6/9)	83.3 %* (5/6)
sFas=<9.6	M30≦1500	33.3% (3/9)	77.8 %* (7/9)	66.7 % (8/12)
	M30≦600	37.5% (3/8)	75.0 % (6/8)	75.0 % (6/8)
	M30≦500	33.3% (2/6)	75.0 % (6/8)	83.3 %* (5/6)
sFas=<9.5	M30≦1500	25.0% (2/8)	77.8 %** (7/9)	66.7 %* (8/12)
	M30≦600	28.6% (2/7)	75.0 %* (6/8)	75.0 %* (6/8)
	M30≦500	20.0% (1/5)	75.0 %* (6/8)	83.3 %** (5/6)

Fig. 18

[Fig. 18-2]

χ square test vs.Placebo * p<0.10 ** p<0.05

p value by χ square test vs. Placebo		Placebo	EPA-E 1800mg/day	EPA-E 2700mg/day
sFas=<10.0	M30≦1500	-	0.133	0.295
	M30≦600	-	0.110	0.342
	M30≦500	-	0.086 *	0.201
sFas=<9.7	M30≦1500	-	0.110	0.193
	M30≦600	-	0.229	0.131
	M30≦500	-	0.205	0.079 *
sFas=<9.6	M30≦1500	-	0.058 *	0.130
	M30≦600	-	0.131	0.131
	M30≦500	-	0.119	0.079 *
sFas=<9.5	M30≦1500	-	0.030 **	0.068 *
	M30≦600	-	0.072 *	0.072 *
	M30≦500	-	0.053 *	0.036 **

Fig. 18 continued

[Fig. 19]

Further Characterization of Patient Group 3: Risk Score※

Proportion of responder of Primary Endpoint

(NAS score≦3or improve≧2 across at least 2 of NAS components)

Proportion of responder (n of responder/n of cases)	Placebo	EPA-E 1800mg/day
Risk Score=<4.000	25.0 % (8/32)	40.6% (13/32)
Risk Score=<3.000	27.6 % (8/29)	50.0 %* (12/24)
Risk Score=<2.859	29.6 % (8/27)	47.8% (11/23)

χ square test vs.Placebo *:p<0.10

p value by χ square test vs. Placebo	Placebo	EPA-E 1800mg/day
Risk Score=<4.000	-	0.183
Risk Score=<3.000	-	0.094*
Risk Score=<2.859	-	0.186

The regression formula for prediction of presence of NASH based on sFas and M30

Risk Score=-6.4894+0.0078xM30(U/L)+0.4668xsFas(ng/mL)

(Tamimi TI., et.al., J. Hepatol., 54, 1224-1229, 2011)

Fig. 19

[Fig. 20]

Parameter (Baseline)	Group	sFas=<9.5	sFas>9.5	Tamimi TI., et.al [a)]
sFas (ng/mL)	Placebo	8.3±0.9	13.2±2.0	· Median (25th,75th percentile) NASH: 11.8 (7.8,12.5) Not NASH: 5.9 (4.8,8.3)
	1800	8.5±1.4	13.2±4.1	
	2700	8.8±0.5	12.7±3.1	
M30 (U/L)	Placebo	537±419	862±902	· Range:60-2306 · Median (25th,75th percentile) NASH: 508 (280,846) Not NASH: 176 (131,224)
	1800	562±642	753±616	
	2700	602±350	813±702	

a) **Tamimi TI., et.al., J. Hepatol., 54, 1224-1229, 2011**

Fig. 20

[Fig. 21]

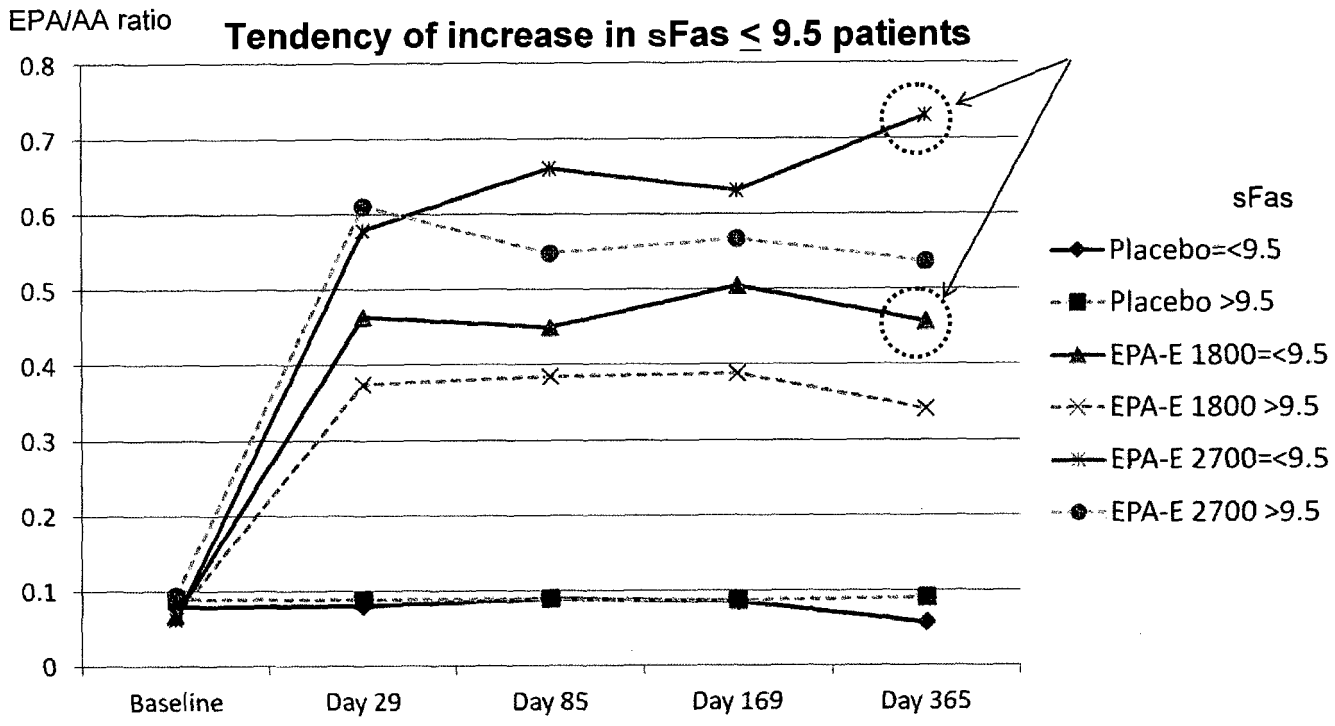

EPA/AA ratio
Tendency of increase in sFas ≤ 9.5 patients
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
Baseline
Day 29
Day 85
Day 169
Day 365
sFas
Placebo=<9.5
Placebo >9.5
EPA-E 1800=<9.5
EPA-E 1800 >9.5
EPA-E 2700=<9.5
EPA-E 2700 >9.5

Fig. 21

[Fig. 22]

EPA/AA ratio at Day365 mean±SD (n)	Placebo	EPA-E 1800mg/day	EPA-E 2700mg/day
All Cases	0.086±0.080 (46)	0.362±0.240 (50)	0.572±0.390 (56)
sFas≦9.5	0.056±0.012 (4)	0.458±0.322* (9)	0.731±0.442* (10)
sFas>9.5	0.088±0.084 (42)	0.341±0.212 (41)	0.537±0.369 (46)

Student's t test vs sFas>9.5 * p<0.10

p value by student's t test	Placebo	EPA-E 1800mg/day	EPA-E 2700mg/day
sFas≦9.5 vs sFas>9.5	0.227	0.097*	0.080*

Fig. 22