Trial record **1 of 1** for: OM-EPA-003
Previous Study | Return to List | Next Study

Epanova® for Lowering Very High Triglycerides (EVOLVE)

This study has been completed.

Sponsor:
AstraZeneca

Information provided by (Responsible Party):
AstraZeneca

ClinicalTrials.gov Identifier:
NCT01242527

First received: November 15, 2010
Last updated: June 24, 2016
Last verified: June 2016
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: June 26, 2013

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Severe Hypertriglyceridemia
Interventions:	Drug: placebo Drug: omefas

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
The enrollment period started April 2011 and the last subject visit was February 2012. All subjects were qualified at the clinical site and eligibility was determined by each PI (74 US and International clinical sites).

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Subjects who needed to washout omega-3 drugs/supplements or adjust or add a permitted statin, CAI or combination had an 8-week screening. All other subjects, including those on a stable statin, CAI or statin-CAI, or who needed to washout of bile acid sequestrants, fibrates, niacin and other lipid altering supplements had a 4-week screening period.

Reporting Groups

	Description
Olive Oil (Placebo Control)	placebo : 4 capsules (1g) daily for 12 weeks
Epanova 2 g	omefas : 2 capsules (1g) + 2 placebo daily for 12 weeks
Epanova 3 g	omefas : 3 capsules (1g) + 1 placebo daily for 12 weeks
Epanova 4 g	omefas : 4 capsules (1g)daily for 12 weeks

Participant Flow: Overall Study

	Olive Oil (Placebo Control)	Epanova 2 g	Epanova 3 g	Epanova 4 g
STARTED	**99**	**100**	**101**	**99**
COMPLETED	**94**	**93**	**87**	**90**

NOT COMPLETED	5	7	14	9

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Olive Oil (Placebo)	placebo : 4 capsules (1g) daily for 12 weeks
Epanova 2 g	omefas : 2 capsules (1g) + 2 placebo daily for 12 weeks
Epanova 3 g	omefas : 3 capsules (1g) + 1 placebo daily for 12 weeks
Epanova 4 g	omefas : 4 capsules (1g)daily for 12 weeks
Total	Total of all reporting groups

Baseline Measures

	Olive Oil (Placebo)	Epanova 2 g	Epanova 3 g	Epanova 4 g	Total
Overall Participants Analyzed [Units: Participants]	**99**	**100**	**101**	**99**	**399**
Age [Units: Years] Mean (Standard Deviation)	**50.8 (10.59)**	**51.1 (9.79)**	**51.2 (8.75)**	**52.9 (10.92)**	**51.5 (10.04)**
Gender [Units: Participants]					
Female	**22**	**20**	**22**	**28**	**92**
Male	**77**	**80**	**79**	**71**	**307**
Ethnicity (NIH/OMB) [Units: Participants]					
Hispanic or Latino	**6**	**8**	**4**	**7**	**25**
Not Hispanic or Latino	**93**	**92**	**97**	**92**	**374**
Unknown or Not Reported	**0**	**0**	**0**	**0**	**0**

Outcome Measures

1. Primary: Fasting Serum Triglycerides [Time Frame: 12 weeks]

Hide Outcome Measure 1

Measure Type	Primary
Measure Title	Fasting Serum Triglycerides
Measure Description	The primary endpoints are the differences in mean percent changes from baseline to end-of-treatment in triglycerides between placebo and the 2g/day, 3g/day and 4g/day Epanova groups
Time Frame	12 weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Intent-to-Treat (ITT) Population was comprised of all subjects who were randomized. In the event that randomized subjects terminated before treatment or had no post-treatment efficacy assessments, a modified ITT Population was implemented.

Reporting Groups

	Description
Olive Oil (Placebo)	placebo : 4 capsules (1g) daily for 12 weeks
Epanova 2 g	omefas : 2 capsules (1g) + 2 placebo daily for 12 weeks
Epanova 3 g	omefas : 3 capsules (1g) + 1 placebo daily for 12 weeks
Epanova 4 g	omefas : 4 capsules (1g)daily for 12 weeks

Measured Values

	Olive Oil (Placebo)	Epanova 2 g	Epanova 3 g	Epanova 4 g
Participants Analyzed [Units: Participants]	**98**	**99**	**97**	**99**
Fasting Serum Triglycerides [Units: Percent change from baseline] Least Squares Mean (95% Confidence Interval)	**-4.26** **(-13.07 to 5.44)**	**-25.94** **(-32.84 to -18.33)**	**-25.46** **(-32.44 to -17.75)**	**-30.86** **(-37.32 to -23.74)**

Statistical Analysis 1 for Fasting Serum Triglycerides

Groups [1]	Olive Oil (Placebo) vs. Epanova 2 g
Method [2]	ANCOVA p-value on ranked data
P Value [3]	0.005
Placebo adjusted % change from baseline [4]	-21.68
95% Confidence Interval	-40.70 to -2.89

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	ANCOVA model with baseline value as covariate, and treatment and user/non-user of lipid-altering drugs as factors
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	P-value adjusted with Dunnett's procedure for multiple comparisons of Epanova vs olive oil
[4]	Other relevant estimation information:
	ANCOVA on log-scale TG with baseline value as covariate and treatment and user/non-user of lipid-altering drugs as factors

Statistical Analysis 2 for Fasting Serum Triglycerides

Groups [1]	Olive Oil (Placebo) vs. Epanova 3 g
Method [2]	ANCOVA p-value on ranked data
P Value [3]	0.007
Placebo adjusted % change from baseline [4]	-21.19
95% Confidence Interval	-40.32 to -2.29

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	ANCOVA model with baseline value as covariate, and treatment and user/non-user of lipid-altering drugs as factors
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	P-value adjusted with Dunnett's procedure for multiple comparisons of Epanova vs olive oil
[4]	Other relevant estimation information:

	ANCOVA on log-scale TG with baseline value as covariate, and treatment and user/non-user of lipid-altering drugs as factors

Statistical Analysis 3 for Fasting Serum Triglycerides

Groups [1]	Olive Oil (Placebo) vs. Epanova 4 g
Method [2]	ANCOVA p-value on ranked data
P Value [3]	<0.001
Placebo adjusted % change from baseline [4]	-26.60
95% Confidence Interval	-45.12 to -8.38

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	ANCOVA model with baseline value as covariate, and treatment and user/non-user of lipid-altering drugs as factors
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	P-value adjusted with Dunnett's procedure for multiple comparisons of Epanova vs olive oil
[4]	Other relevant estimation information:
	ANCOVA on log-scale TG with baseline value as covariate, and treatment and user/non-user of lipid-altering drugs as factors

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
Olive Oil (Placebo)	placebo : 4 capsules (1g) daily for 12 weeks
Epanova 2 g	omefas : 2 capsules (1g) + 2 placebo daily for 12 weeks
Epanova 3 g	omefas : 3 capsules (1g) + 1 placebo daily for 12 weeks
Epanova 4 g	omefas : 4 capsules (1g)daily for 12 weeks

Serious Adverse Events

	Olive Oil (Placebo)	Epanova 2 g	Epanova 3 g	Epanova 4 g
Total, serious adverse events				
# participants affected / at risk	**2/99 (2.02%)**	**1/100 (1.00%)**	**4/101 (3.96%)**	**0/99 (0.00%)**
Cardiac disorders				
Myocarditis † 1				
# participants affected / at risk	**1/99 (1.01%)**	**0/100 (0.00%)**	**0/101 (0.00%)**	**0/99 (0.00%)**
# events	**1**	**0**	**0**	**0**
Angina pectoris † 1				
# participants affected / at risk	**0/99 (0.00%)**	**1/100 (1.00%)**	**1/101 (0.99%)**	**0/99 (0.00%)**
# events	**0**	**1**	**1**	**0**
Coronary artery disease † 1				
# participants affected / at risk	**0/99 (0.00%)**	**0/100 (0.00%)**	**1/101 (0.99%)**	**0/99 (0.00%)**
# events	**0**	**0**	**1**	**0**
Implantable defibrillator insertion † 1				
# participants affected / at risk	**0/99 (0.00%)**	**0/100 (0.00%)**	**1/101 (0.99%)**	**0/99 (0.00%)**
# events	**0**	**0**	**1**	**0**
Gastrointestinal disorders				

Abdominal pain † 1				
# participants affected / at risk	1/99 (1.01%)	0/100 (0.00%)	0/101 (0.00%)	0/99 (0.00%)
# events	1	0	0	0
Respiratory, thoracic and mediastinal disorders				
Pulmonary embolism † 1				
# participants affected / at risk	0/99 (0.00%)	0/100 (0.00%)	1/101 (0.99%)	0/99 (0.00%)
# events	0	0	1	0

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 14.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5

Reporting Groups

	Description
Olive Oil (Placebo)	placebo : 4 capsules (1g) daily for 12 weeks
Epanova 2 g	omefas : 2 capsules (1g) + 2 placebo daily for 12 weeks
Epanova 3 g	omefas : 3 capsules (1g) + 1 placebo daily for 12 weeks
Epanova 4 g	omefas : 4 capsules (1g)daily for 12 weeks

Other Adverse Events

	Olive Oil (Placebo)	Epanova 2 g	Epanova 3 g	Epanova 4 g
Total, other (not including serious) adverse events				
# participants affected / at risk	5/99 (5.05%)	23/100 (23.00%)	18/101 (17.82%)	16/99 (16.16%)
Gastrointestinal disorders				
Diarrhoea † 1				
# participants affected / at risk	2/99 (2.02%)	10/100 (10.00%)	6/101 (5.94%)	10/99 (10.10%)
# events	3	12	7	11
Nausea † 1				
# participants affected / at risk	1/99 (1.01%)	6/100 (6.00%)	9/101 (8.91%)	5/99 (5.05%)
# events	1	9	11	5
Infections and infestations				
Nasopharyngitis † 1				
# participants affected / at risk	2/99 (2.02%)	7/100 (7.00%)	3/101 (2.97%)	1/99 (1.01%)
# events	3	7	3	1

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 14.1

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

☑ **Restriction Description:** Individual investigators may publish data arising from their own subjects. The PI will provide the Sponsor with copies of written publications (including abstracts and posters)at least 60 days in advance of submission. Data will be reviewed by all participating investigators prior to publication. The Sponsor will have 60 days to review all definitive publications, such as manuscripts and book chapters, and a minimum of 30 days to review all abstracts.

Results Point of Contact:

Name/Title: Torbjörn Lundström, Medical Science Director
Organization: AstraZeneca Pharmaceuticals
e-mail: ClinicalTrialTransparency@astrazeneca.com

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Kastelein JJ, Maki KC, Susekov A, Ezhov M, Nordestgaard BG, Machielse BN, Kling D, Davidson MH. Omega-3 free fatty acids for the treatment of severe hypertriglyceridemia: the EpanoVa fOr Lowering Very high triglyceridEs (EVOLVE) trial. J Clin Lipidol. 2014 Jan-Feb;8(1):94-106. doi: 10.1016/j.jacl.2013.10.003.

Responsible Party:	AstraZeneca
ClinicalTrials.gov Identifier:	NCT01242527 History of Changes
Other Study ID Numbers:	**OM-EPA-003**
Study First Received:	November 15, 2010
Results First Received:	June 26, 2013
Last Updated:	June 24, 2016
Health Authority:	United States: Food and Drug Administration Hungary: National Institute of Pharmacy Denmark: Ethics Committee Netherlands: Medical Ethics Review Committee (METC) Russia: Ministry of Health of the Russian Federation India: Drugs Controller General of India