Clinical trial results:
A THREE YEAR, PROSPECTIVE, OPEN-LABEL, STUDY TO EVALUATE CLINICAL EFFICACY, SAFETY AND TOLERABILITY OF ATORVASTATIN IN CHILDREN AND ADOLESCENTS WITH HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA

Summary

EudraCT number	2008-006130-95
Trial protocol	ES HU BE IT DE GR SK Outside EU/EEA
Global end of trial date	08 October 2013

Results information

Result version number	v2 (current)
This version publication date	12 May 2016
First version publication date	25 June 2015
Version creation reason	• Correction of full data set Reporting periods and duplicate Adverse Events in their data.

Trial information

Trial identification

Sponsor protocol code	A2581173

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00827606
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, NY 10017
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc, 00 1-800-718-1021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc, 00 1-800-718-1021, ClinicalTrials.gov_Inquiries@pfizer.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-000073-PIP01-07
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	26 February 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	08 October 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To characterize long-term (three year) descriptive growth development (i.e., height, weight, body mass index, Tanner Stage) in pediatric subjects with heterozygous familial hypercholesterolemia (HeFH) receiving atorvastatin treatment.

To characterize long-term, three year descriptive efficacy (low-density lipoprotein cholesterol [LDL-C], total cholesterol [TC], triglycerides [TG], high-density lipoprotein [HDL], very low-density lipoprotein [VLDL], apolipoprotein A-1 [Apo A-1], apolipoprotein B [Apo B]), tolerability and safety in pediatric subjects with HeFH receiving atorvastatin treatment.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 March 2009
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Switzerland: 8
Country: Number of subjects enrolled	Norway: 25
Country: Number of subjects enrolled	Poland: 10
Country: Number of subjects enrolled	Slovakia: 16
Country: Number of subjects enrolled	Spain: 25
Country: Number of subjects enrolled	Belgium: 16
Country: Number of subjects enrolled	Germany: 2
Country: Number of subjects enrolled	Greece: 40
Country: Number of subjects enrolled	Hungary: 14
Country: Number of subjects enrolled	Italy: 14
Country: Number of subjects enrolled	Canada: 27
Country: Number of subjects enrolled	United States: 50
Country: Number of subjects enrolled	Russian Federation: 6
Country: Number of subjects enrolled	Turkey: 18

Worldwide total number of subjects	271
EEA total number of subjects	162

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	177
Adolescents (12-17 years)	94
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

The study started on 30 March 2009 and ended on 08 October 2013 in Belgium, Canada, Switzerland, Germany, Spain, Greece, Hungry, Italy, Norway, Poland , Russian Federation, Slovakia, Turkey, United States.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Atorvastatin (5-80 mg): Tanner_Stage 1

Arm description:

Subjects aged 6 to less than (<)10 years, at Tanner_Stage 1 received an initial dose of atorvastatin tablets, 5 milligrams per day (mg/day), orally (PO), through Week 4; after Week 4, dose may have been doubled to 10 mg/day, with subsequent doubling to 20 mg/day (as necessary; maximum dose was 80 mg/day), PO, if target LDL-C (<3.35 millimoles per liter [mmol/L]) was not attained.

Arm type	Experimental
Investigational medicinal product name	Atorvastatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Chewable tablet
Routes of administration	Oral use

Dosage and administration details:

Initial dose of 5 mg/day of atorvastatin was administered PO, through Week 4; after Week 4, dose may have been doubled to 10 mg/day, with subsequent doubling to 20 mg/day (as necessary; maximum dose was 80 mg/day)

Arm title	Atorvastatin (10-80 mg): Tanner_Stage 2+

Arm description:

Subjects aged greater than or equal to (≥) 10 to 15 years, at Tanner_Stage 2+ received an initial dose of atorvastatin tablets, 10 mg/day, PO, through Week 4; after Week 4, dose may have been doubled to 20 mg/day, with subsequent doubling to 40 mg/day (as necessary; maximum dose was 80 mg/day), PO, if target LDL-C (<3.35 mmol/L) was not attained.

Arm type	Experimental
Investigational medicinal product name	Atorvastatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Chewable tablet
Routes of administration	Oral use

Dosage and administration details:

Initial dose of 10 mg/day of atorvastatin was administered PO, through Week 4; after Week 4, dose may have been doubled to 20 mg/day, with subsequent doubling to 40 mg/day (as necessary; maximum dose was 80 mg/day).

Number of subjects in period 1	Atorvastatin (5-80 mg): Tanner_Stage 1	Atorvastatin (10-80 mg): Tanner_Stage 2+
Started	139	132
Completed	112	94
Not completed	27	38
Consent withdrawn by subject	7	6
Adverse events	4	2
Protocol violation	4	3
Not specified	5	13
Pregnancy	-	1
Lost to follow-up	3	1
LDL below 2.59 mmol/L	4	12

Baseline characteristics

Reporting groups	
Reporting group title	Atorvastatin (5-80 mg): Tanner_Stage 1
Reporting group description:	
Subjects aged 6 to less than (<)10 years, at Tanner_Stage 1 received an initial dose of atorvastatin tablets, 5 milligrams per day (mg/day), orally (PO), through Week 4; after Week 4, dose may have been doubled to 10 mg/day, with subsequent doubling to 20 mg/day (as necessary; maximum dose was 80 mg/day), PO, if target LDL-C (<3.35 millimoles per liter [mmol/L]) was not attained.	
Reporting group title	Atorvastatin (10-80 mg): Tanner_Stage 2+
Reporting group description:	
Subjects aged greater than or equal to (≥) 10 to 15 years, at Tanner_Stage 2+ received an initial dose of atorvastatin tablets, 10 mg/day, PO, through Week 4; after Week 4, dose may have been doubled to 20 mg/day, with subsequent doubling to 40 mg/day (as necessary; maximum dose was 80 mg/day), PO, if target LDL-C (<3.35 mmol/L) was not attained.	

Reporting group values	Atorvastatin (5-80 mg): Tanner_Stage 1	Atorvastatin (10-80 mg): Tanner_Stage 2+	Total
Number of subjects	139	132	271
Age categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean	8.5	12	
standard deviation	± 1.86	± 1.68	-
Gender categorical			
Units: Subjects			
Female	46	79	125
Male	93	53	146

End points

End points reporting groups

Reporting group title	Atorvastatin (5-80 mg): Tanner_Stage 1

Reporting group description:

Subjects aged 6 to less than (<)10 years, at Tanner_Stage 1 received an initial dose of atorvastatin tablets, 5 milligrams per day (mg/day), orally (PO), through Week 4; after Week 4, dose may have been doubled to 10 mg/day, with subsequent doubling to 20 mg/day (as necessary; maximum dose was 80 mg/day), PO, if target LDL-C (<3.35 millimoles per liter [mmol/L]) was not attained.

Reporting group title	Atorvastatin (10-80 mg): Tanner_Stage 2+

Reporting group description:

Subjects aged greater than or equal to (≥) 10 to 15 years, at Tanner_Stage 2+ received an initial dose of atorvastatin tablets, 10 mg/day, PO, through Week 4; after Week 4, dose may have been doubled to 20 mg/day, with subsequent doubling to 40 mg/day (as necessary; maximum dose was 80 mg/day), PO, if target LDL-C (<3.35 mmol/L) was not attained.

Subject analysis set title	Atorvastatin (10-80 mg): Baseline Tanner_Stage 4
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects aged ≥10 to 15 years, at Tanner_Stage 4 received an initial dose of atorvastatin tablets, 10 mg/day, PO, through Week 4; after Week 4, dose may have been doubled to 20 mg/day, PO, with subsequent doubling to 40 mg/day (as necessary; maximum dose was 80 mg/day), PO, if target LDL-C (<3.35 mmol/L) was not attained.

Subject analysis set title	Atorvastatin (10-80 mg): Baseline Tanner_Stage 3
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects aged ≥10 to 15 years, at Tanner_Stage 3 received an initial dose of atorvastatin tablets, 10 mg/day, PO, through Week 4; after Week 4, dose may have been doubled to 20 mg/day, PO, with subsequent doubling to 40 mg/day (as necessary; maximum dose was 80 mg/day), PO, if target LDL-C (<3.35 mmol/L) was not attained.

Subject analysis set title	Atorvastatin (10-80 mg): Baseline Tanner_Stage 2
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects aged ≥10 to 15 years, at Tanner_Stage 2 received an initial dose of atorvastatin tablets, 10 mg/day, PO, through Week 4; after Week 4, dose may have been doubled to 20 mg/day, with subsequent doubling to 40 mg/day (as necessary; maximum dose was 80 mg/day), PO, if target LDL-C (<3.35 mmol/L) was not attained.

Subject analysis set title	Atorvastatin (10-80 mg): Baseline Tanner_Stage 5
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects aged ≥10 to 15 years, at Tanner_Stage 5 received an initial dose of atorvastatin tablets, 10 mg/day, PO, through Week 4; after Week 4, dose may have been doubled to 20 mg/day, PO, with subsequent doubling to 40 mg/day (as necessary; maximum dose was 80 mg/day), PO, if target LDL-C (<3.35 mmol/L) was not attained.

Subject analysis set title	Atorvastatin (5-80 mg)
Subject analysis set type	Full analysis

Subject analysis set description:

Subjects aged 6 to <10 years, at Tanner_Stage 1 received an initial dose of atorvastatin tablets, 5 mg/day, PO, through Week 4; after Week 4, dose may have been doubled to 10 mg/day, PO, with subsequent doubling to 20 mg/day (as necessary; maximum dose was 80 mg/day), PO, if target LDL-C (<3.35 mmol/L) was not attained. Subjects aged ≥10 to 15 years, at Tanner_Stage 2+ received an initial dose of atorvastatin tablets, 10 mg/day, PO, through Week 4; after Week 4, dose may have been doubled to 20 mg/day, with subsequent doubling to 40 mg/day (as necessary; maximum dose was 80 mg/day), PO, if target LDL-C (<3.35 mmol/L) was not attained.

Primary: Low Density Lipoprotein Cholesterol (LDL-C; millimoles per liter [mmol/L]) During the Study

End point title	Low Density Lipoprotein Cholesterol (LDL-C; millimoles per liter [mmol/L]) During the Study[1]

End point description:

Assessments were performed in the fasting state (minimum 10-hour fast). Change from baseline was also determined. Full analysis set (FAS); n (number) equals (=) number of subjects assessed for the specified parameter at a given visit.

End point type	Primary

End point timeframe:

Baseline, Months 1, 2, 3, 6, 12, 18, 24, 30 and 36 (or early termination [ET])

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Atorvastatin (5-80 mg): Tanner_Stage 1	Atorvastatin (10-80 mg): Tanner_Stage 2+		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	139	132		
Units: mmol/L				
arithmetic mean (standard deviation)				
Baseline (n=139,132)	6.304 (± 1.313)	5.921 (± 1.1646)		
Month 1 (n=131,130)	4.087 (± 1.0264)	3.675 (± 0.8749)		
Change at Month 1 (n=131,130)	-2.214 (± 0.7568)	-2.233 (± 0.8009)		
Month 2 (n=132,122)	3.719 (± 0.8346)	3.437 (± 0.7438)		
Change at Month 2 (n=132,122)	-2.586 (± 0.9297)	-2.554 (± 0.9155)		
Month 3 (n=126,117)	3.503 (± 0.7566)	3.27 (± 0.6533)		
Change at Month 3 (n=126,117)	-2.798 (± 1.0251)	-2.795 (± 1.0835)		
Month 6 (n=127,115)	3.366 (± 0.5787)	3.347 (± 0.5953)		
Change at Month 6 (n=127,115)	-2.968 (± 1.1096)	-2.732 (± 1.066)		
Month 12 (n=121,109)	3.409 (± 0.7395)	3.196 (± 0.6565)		
Change at Month 12 (n=121,109)	-2.966 (± 1.0987)	-2.838 (± 1.145)		
Month 18 (n=116,101)	3.309 (± 0.5933)	3.261 (± 0.5288)		
Change at Month 18 (n=116,101)	-3.105 (± 1.1558)	-2.835 (± 1.2128)		
Month 24 (n=111,96)	3.316 (± 0.6803)	3.189 (± 0.6537)		
Change at Month 24 (n=111,96)	-3.088 (± 1.2026)	-2.933 (± 1.2292)		
Month 30 (n=112,94)	3.335 (± 0.649)	3.142 (± 0.6916)		
Change at Month 30 (n=112,94)	-3.09 (± 1.2402)	-3.008 (± 1.1489)		

Month 36/ET (n=123,117)	3.45 (± 0.7372)	3.457 (± 0.8808)		
Change at Month 36/ET (n=123,117)	-2.855 (± 1.2625)	-2.468 (± 1.327)		

Statistical analyses

No statistical analyses for this end point

Primary: Percent Change from Baseline in LDL-C

End point title	Percent Change from Baseline in LDL-C[2]

End point description:

Assessments were performed in the fasting state (minimum 10-hour fast). FAS; n=number of subjects assessed for the specified parameter at a given visit.

End point type	Primary

End point timeframe:

Months 1, 2, 3, 6, 12, 18, 24, 30 and 36 (or ET)

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Atorvastatin (5-80 mg): Tanner_Stage 1	Atorvastatin (10-80 mg): Tanner_Stage 2+		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	132	130		
Units: percent change				
arithmetic mean (standard deviation)				
Month 1 (n=131,130)	-34.995 (± 9.73)	-37.516 (± 10.0245)		
Month 2 (n=132,122)	-40.371 (± 9.6468)	-41.939 (± 10.4816)		
Month 3 (n=126,117)	-43.568 (± 10.2149)	-44.887 (± 12.753)		
Month 6 (n=127,115)	-45.647 (± 9.6969)	-43.697 (± 11.1836)		
Month 12 (n=121,109)	-45.53 (± 10.5112)	-45.727 (± 13.5336)		
Month 18 (n=116,101)	-47.101 (± 10.5592)	-44.818 (± 13.2623)		
Month 24 (n=111,96)	-46.944 (± 11.949)	-46.417 (± 13.8658)		
Month 30 (n=112,94)	-46.631 (± 12.0206)	-47.734 (± 12.6696)		
Month 36/ET (n=123,117)	-43.785 (± 13.5585)	-39.863 (± 17.5411)		

Statistical analyses

No statistical analyses for this end point

Primary: High-Density Lipoprotein Cholesterol (HDL-C; mmol/L) During the Study

End point title	High-Density Lipoprotein Cholesterol (HDL-C; mmol/L) During the Study[3]

End point description:

Assessments were performed in the fasting state (minimum 10-hour fast). Change from baseline was also determined. FAS; n=number of subjects assessed for the specified parameter at a given visit.

End point type	Primary

End point timeframe:

Baseline, Months 1, 2, 3, 6, 12, 18, 24, 30 and 36/ET

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Atorvastatin (5-80 mg): Tanner_Stage 1	Atorvastatin (10-80 mg): Tanner_Stage 2+		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	139	132		
Units: mmol/L				
arithmetic mean (standard deviation)				
Baseline (n=139,132)	1.349 (± 0.2732)	1.277 (± 0.2546)		
Month 1 (n=131,130)	1.36 (± 0.2717)	1.292 (± 0.265)		
Change at Month 1 (n=131,130)	0.01 (± 0.1685)	0.016 (± 0.174)		
Month 2 (n=132,122)	1.364 (± 0.2805)	1.297 (± 0.2625)		
Change at Month 2 (n=132,122)	0.014 (± 0.2238)	0.025 (± 0.16)		
Month 3 (n=126,117)	1.371 (± 0.2768)	1.274 (± 0.2606)		
Change at Month 3 (n=126,117)	0.015 (± 0.1943)	0.011 (± 0.1837)		
Month 6 (n=127,115)	1.337 (± 0.2834)	1.268 (± 0.2311)		
Change at Month 6 (n=127,115)	-0.011 (± 0.1848)	0.01 (± 0.1833)		
Month 12 (n=121,109)	1.328 (± 0.2885)	1.241 (± 0.2429)		
Change at Month 12 (n=121,109)	-0.012 (± 0.1945)	-0.023 (± 0.1727)		
Month 18 (n=116,102)	1.367 (± 0.3003)	1.234 (± 0.2349)		
Change at Month 18 (n=116,102)	0.024 (± 0.1923)	-0.027 (± 0.1744)		
Month 24 (n=111,96)	1.385 (± 0.2729)	1.266 (± 0.2443)		
Change at Month 24 (n=111,96)	0.027 (± 0.2043)	0.007 (± 0.191)		
Month 30 (n=112,94)	1.38 (± 0.2942)	1.265 (± 0.2487)		
Change at Month 30 (n=112,94)	0.032 (± 0.1997)	0.006 (± 0.215)		

Month 36/ET (n=123,117)	1.335 (± 0.2918)	1.278 (± 0.2516)		
Change at Month 36/ET (n=123,117)	-0.024 (± 0.1949)	0.005 (± 0.1975)		

Statistical analyses

No statistical analyses for this end point

Primary: Percent Change from Baseline in HDL-C

End point title	Percent Change from Baseline in HDL-C[4]

End point description:

Assessments were performed in the fasting state (minimum 10-hour fast). FAS; n=number of subjects assessed for the specified parameter at a given visit.

End point type	Primary

End point timeframe:

Months 1, 2, 3, 6, 12, 18, 24, 30 and 36/ET

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Atorvastatin (5-80 mg): Tanner_Stage 1	Atorvastatin (10-80 mg): Tanner_Stage 2+		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	132	130		
Units: percent change				
arithmetic mean (standard deviation)				
Month 1 (n=131,130)	1.526 (± 12.7845)	2.192 (± 14.0769)		
Month 2 (n=132,122)	2.195 (± 15.6882)	2.544 (± 12.7802)		
Month 3 (n=126,117)	1.929 (± 14.7329)	1.674 (± 14.9525)		
Month 6 (n=127,115)	-0.016 (± 14.8853)	1.877 (± 14.9113)		
Month 12 (n=121,109)	-0.069 (± 15.2821)	-1.023 (± 14.1983)		
Month 18 (n=116,102)	2.472 (± 14.8939)	-1.165 (± 14.3783)		
Month 24 (n=111,96)	3.014 (± 14.9559)	1.737 (± 15.6924)		
Month 30 (n=112,94)	3.345 (± 15.508)	1.868 (± 17.2633)		
Month 36/ET (n=123,117)	-1.125 (± 14.7816)	1.602 (± 15.4895)		

Statistical analyses

No statistical analyses for this end point

Primary: Total Cholesterol (mmol/L) During the Study

End point title	Total Cholesterol (mmol/L) During the Study[5]

End point description:

Assessments were performed in the fasting state (minimum 10-hour fast). Change from baseline was also determined. FAS; n=number of subjects assessed for the specified parameter at a given visit.

End point type	Primary

End point timeframe:

Baseline, Months 1, 2, 3, 6, 12, 18, 24, 30 and 36/ET

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Atorvastatin (5-80 mg): Tanner_Stage 1	Atorvastatin (10-80 mg): Tanner_Stage 2+		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	139	132		
Units: mmol/L				
arithmetic mean (standard deviation)				
Baseline (n=139,132)	8.056 (± 1.3356)	7.647 (± 1.225)		
Month 1 (n=134,131)	5.785 (± 1.0497)	5.352 (± 0.9345)		
Change at Month 1 (n=134,131)	-2.266 (± 0.7957)	-2.297 (± 0.8516)		
Month 2 (n=132,124)	5.435 (± 0.8629)	5.061 (± 0.7865)		
Change at Month 2 (n=132,124)	-2.62 (± 0.9581)	-2.654 (± 0.9707)		
Month 3 (n=127,118)	5.195 (± 0.8)	4.883 (± 0.7034)		
Change at Month 3 (n=127,118)	-2.869 (± 1.0904)	-2.883 (± 1.1363)		
Month 6 (n=127,115)	5.019 (± 0.638)	4.982 (± 0.662)		
Change at Month 6 (n=127,115)	-3.063 (± 1.1687)	-2.809 (± 1.1133)		
Month 12 (n=121,109)	5.081 (± 0.747)	4.799 (± 0.7176)		
Change at Month 12 (n=121,109)	-3.04 (± 1.1353)	-2.945 (± 1.2112)		
Month 18 (n=116,101)	4.989 (± 0.6512)	4.845 (± 0.5401)		
Change at Month 18 (n=116,101)	-3.168 (± 1.199)	-2.965 (± 1.2667)		
Month 24 (n=111,96)	5.032 (± 0.7111)	4.817 (± 0.7413)		
Change at Month 24 (n=111,96)	-3.123 (± 1.2039)	-3.009 (± 1.2871)		
Month 30 (n=112,95)	5.075 (± 0.6951)	4.795 (± 0.8256)		
Change at Month 30 (n=112,95)	-3.096 (± 1.2999)	-3.048 (± 1.2716)		

Month 36/ET (n=123,117)	5.134 (± 0.7863)	5.099 (± 0.9318)		
Change at Month 36/ET (n=123,117)	-2.923 (± 1.3256)	-2.543 (± 1.3669)		

Statistical analyses

No statistical analyses for this end point

Primary: Percent Change from Baseline in Total Cholesterol

End point title	Percent Change from Baseline in Total Cholesterol[6]

End point description:

Assessments were performed in the fasting state (minimum 10-hour fast). FAS; n=number of subjects assessed for the specified parameter at a given visit.

End point type	Primary

End point timeframe:

Months 1, 2, 3, 6, 12, 18, 24, 30 and 36/ET

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Atorvastatin (5-80 mg): Tanner_Stage 1	Atorvastatin (10-80 mg): Tanner_Stage 2+		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	134	131		
Units: percent change				
arithmetic mean (standard deviation)				
Month 1 (n=134,131)	-27.879 (± 8.2639)	-29.653 (± 8.5987)		
Month 2 (n=132,124)	-31.9 (± 8.5025)	-33.726 (± 9.2319)		
Month 3 (n=127,118)	-34.784 (± 9.4141)	-36.126 (± 11.0136)		
Month 6 (n=127,115)	-36.889 (± 9.2297)	35.055 (± 10.0273)		
Month 12 (n=121,109)	-36.541 (± 9.2486)	-36.943 (± 11.9418)		
Month 18 (n=116,101)	-37.772 (± 9.7325)	-36.634 (± 11.4572)		
Month 24 (n=111,96)	-37.287 (± 9.9578)	-37.317 (± 12.2461)		
Month 30 (n=112,95)	-36.662 (± 11.2064)	-37.856 (± 12.5116)		
Month 36/ET (n=123,117)	-35.063 (± 12.0345)	-32.013 (± 14.5)		

Statistical analyses

No statistical analyses for this end point

Primary: Trigylcerides (mmol/L) During the Study

End point title	Trigylcerides (mmol/L) During the Study[7]

End point description:

Assessments were performed in the fasting state (minimum 10-hour fast). Change from baseline was also determined. FAS; n=number of subjects assessed for the specified parameter at a given visit.

End point type	Primary

End point timeframe:

Baseline, Months 1, 2, 3, 6, 12, 18, 24, 30 and 36/ET

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Atorvastatin (5-80 mg): Tanner_Stage 1	Atorvastatin (10-80 mg): Tanner_Stage 2+		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	139	132		
Units: mmol/L				
arithmetic mean (standard deviation)				
Baseline (n=139,132)	0.88 (± 0.4343)	0.98 (± 0.4986)		
Month 1 (n=134,131)	0.759 (± 0.3958)	0.815 (± 0.3848)		
Change at Month 1 (n=134,131)	-0.121 (± 0.3895)	-0.166 (± 0.5024)		
Month 2 (n=132,124)	0.772 (± 0.3837)	0.741 (± 0.3382)		
Change at Month 2 (n=132,124)	-0.103 (± 0.3652)	-0.246 (± 0.4825)		
Month 3 (n=127,118)	0.699 (± 0.2916)	0.748 (± 0.3357)		
Change at Month 3 (n=127,118)	-0.166 (± 0.3937)	-0.237 (± 0.4466)		
Month 6 (n=127,115)	0.691 (± 0.3602)	0.801 (± 0.3848)		
Change at Month 6 (n=127,115)	-0.183 (± 0.4305)	-0.188 (± 0.488)		
Month 12 (n=121,109)	-0.747 (± 0.3901)	0.789 (± 0.405)		
Change at Month 12 (n=121,109)	-0.136 (± 0.406)	-0.181 (± 0.5255)		
Month 18 (n=116,102)	0.687 (± 0.3435)	0.765 (± 0.3438)		
Change at Month 18 (n=116,102)	-0.19 (± 0.3665)	-0.219 (± 0.4623)		
Month 24 (n=111,96)	0.725 (± 0.3676)	0.79 (± 0.3651)		
Change at Month 24 (n=111,96)	-0.133 (± 0.4112)	-0.179 (± 0.4956)		
Month 30 (n=112,95)	0.788 (± 0.3454)	0.781 (± 0.4167)		
Change at Month 30 (n=112,95)	-0.082 (± 0.3898)	-0.187 (± 0.5728)		

Month 36/ET (n=123,117)	0.764 (± 0.422)	0.794 (± 0.3894)		
Change at Month 36/ET (n=123,117)	-0.092 (± 0.4615)	-0.171 (± 0.5216)		

Statistical analyses

No statistical analyses for this end point

Primary: Percent Change from Baseline in Trigylcerides

End point title	Percent Change from Baseline in Trigylcerides[8]

End point description:

Assessments were performed in the fasting state (minimum 10-hour fast). FAS; n=number of subjects assessed for the specified parameter at a given visit.

End point type	Primary

End point timeframe:

Months 1, 2, 3, 6, 12, 18, 24, 30 and 36/ET

Notes:

[8] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Atorvastatin (5-80 mg): Tanner_Stage 1	Atorvastatin (10-80 mg): Tanner_Stage 2+		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	134	131		
Units: percent change				
arithmetic mean (standard deviation)				
Month 1 (n=134,131)	-5.95 (± 39.0995)	-5.927 (± 51.1811)		
Month 2 (n=132,124)	-3.26 (± 42.5136)	-14.832 (± 40.4952)		
Month 3 (n=127,118)	-8.76 (± 41.1184)	-14.415 (± 39.9951)		
Month 6 (n=127,115)	-11.817 (± 41.9879)	-9.097 (± 43.035)		
Month 12 (n=121,109)	-7.981 (± 40.4511)	-7.95 (± 48.7238)		
Month 18 (n=116,102)	-13.113 (± 39.399)	-12.443 (± 37.3822)		
Month 24 (n=111,96)	-6.697 (± 38.7027)	-7.328 (± 45.3694)		
Month 30 (n=112,95)	0.657 (± 43.3886)	-4.935 (± 63.1887)		
Month 36/ET (n=123,117)	-0.703 (± 50.6333)	-7.759 (± 45.6372)		

Statistical analyses

No statistical analyses for this end point

Primary: Very Low-Density Lipoprotein (VLDL; mmol/L) During the Study

End point title	Very Low-Density Lipoprotein (VLDL; mmol/L) During the Study[9]

End point description:

Assessments were performed in the fasting state (minimum 10-hour fast). Change from baseline was also determined. FAS; n=number of subjects assessed for the specified parameter at a given visit.

End point type	Primary

End point timeframe:

Baseline, Months 1, 2, 3, 6, 12, 18, 24, 30 and 36/ET

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Atorvastatin (5-80 mg): Tanner_Stage 1	Atorvastatin (10-80 mg): Tanner_Stage 2+		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	139	132		
Units: mmol/L				
arithmetic mean (standard deviation)				
Baseline (n=139,132)	0.403 (± 0.1993)	0.449 (± 0.2288)		
Month 1 (n=134,131)	0.348 (± 0.1823)	0.374 (± 0.177)		
Change at Month 1 (n=134,131)	-0.056 (± 0.1793)	-0.076 (± 0.2307)		
Month 2 (n=132,124)	0.354 (± 0.1757)	0.34 (± 0.1541)		
Change at Month 2 (n=132,124)	-0.047 (± 0.1672)	-0.113 (± 0.2215)		
Month 3 (n=127,118)	0.32 (± 0.1333)	0.344 (± 0.1548)		
Change at Month 3 (n=127,118)	-0.076 (± 0.1805)	-0.108 (± 0.2044)		
Month 6 (n=127,115)	0.317 (± 0.1652)	0.367 (± 0.1767)		
Change at Month 6 (n=127,115)	-0.084 (± 0.1977)	-0.086 (± 0.224)		
Month 12 (n=121,109)	0.343 (± 0.1786)	0.362 (± 0.1862)		
Change at Month 12 (n=121,109)	-0.062 (± 0.1872)	-0.082 (± 0.2421)		
Month 18 (n=116,101)	0.315 (± 0.1571)	0.349 (± 0.1571)		
Change at Month 18 (n=116,101)	-0.087 (± 0.168)	-0.102 (± 0.2126)		
Month 24 (n=111,96)	0.332 (± 0.168)	0.363 (± 0.168)		
Change at Month 24 (n=111,96)	-0.061 (± 0.1887)	-0.081 (± 0.2285)		
Month 30 (n=112,95)	0.361 (± 0.1581)	0.358 (± 0.1914)		
Change at Month 30 (n=112,95)	-0.038 (± 0.1781)	-0.086 (± 0.2621)		

Month 36/ET (n=123,117)	0.35 (± 0.193)	0.364 (± 0.1782)		
Change at Month 36/ET (n=123,117)	-0.042 (± 0.2112)	-0.079 (± 0.2385)		

Statistical analyses

No statistical analyses for this end point

Primary: Percent Change from Baseline in VLDL

End point title	Percent Change from Baseline in VLDL[10]

End point description:

Assessments were performed in the fasting state (minimum 10-hour fast). FAS; n=number of subjects assessed for the specified parameter at a given visit.

End point type	Primary

End point timeframe:

Months 1, 2, 3, 6, 12, 18, 24, 30 and 36/ET

Notes:

[10] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Atorvastatin (5-80 mg): Tanner_Stage 1	Atorvastatin (10-80 mg): Tanner_Stage 2+		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	134	131		
Units: percent change				
arithmetic mean (standard deviation)				
Month 1 (n=134,131)	-6.06 (± 39.33)	-5.805 (± 51.7264)		
Month 2 (n=132,124)	-3.097 (± 42.3626)	-14.694 (± 40.171)		
Month 3 (n=127,118)	-8.711 (± 41.2631)	-14.263 (± 39.7239)		
Month 6 (n=127,115)	-11.591 (± 42.4219)	-9.158 (± 43.1397)		
Month 12 (n=121,109)	-7.739 (± 40.7579)	-7.827 (± 48.9819)		
Month 18 (n=116,101)	-12.911 (± 39.7908)	-12.768 (± 37.4142)		
Month 24 (n=111,96)	-6.654 (± 38.7945)	-6.92 (± 46.3317)		
Month 30 (n=112,95)	0.627 (± 43.6239)	-4.751 (± 64.2502)		
Month 36/ET (n=123,117)	-0.52 (± 51.3422)	-7.842 (± 45.464)		

Statistical analyses

No statistical analyses for this end point

Primary: Apolipoprotein A-1 (Apo A-1; grams per liter [g/L]) During the Study

End point title	Apolipoprotein A-1 (Apo A-1; grams per liter [g/L]) During the Study[11]

End point description:

Assessments were performed in the fasting state (minimum 10-hour fast). Change from baseline was also determined. FAS; n=number of subjects assessed for the specified parameter at a given visit.

End point type	Primary

End point timeframe:

Baseline, Months 1, 2, 3, 6, 12, 18, 24, 30 and 36/ET

Notes:

[11] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Atorvastatin (5-80 mg): Tanner_Stage 1	Atorvastatin (10-80 mg): Tanner_Stage 2+		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	138	132		
Units: g/L				
arithmetic mean (standard deviation)				
Baseline (n=138,132)	1.396 (± 0.1839)	1.308 (± 0.2006)		
Month 1 (n=132,130)	1.419 (± 0.2233)	1.337 (± 0.1927)		
Change at Month 1 (n=132,130)	0.025 (± 0.1639)	0.032 (± 0.1506)		
Month 2 (n=131,123)	1.411 (± 0.1952)	1.334 (± 0.195)		
Change at Month 2 (n=131,123)	0.016 (± 0.1519)	0.025 (± 0.1355)		
Month 3 (n=126,117)	1.405 (± 0.1914)	1.306 (± 0.1919)		
Change at Month 3 (n=126,117)	0.005 (± 0.1713)	0.006 (± 0.1557)		
Month 6 (n=123,110)	1.386 (± 0.2081)	1.329 (± 0.1894)		
Change at Month 6 (n=123,110)	-0.007 (± 0.1609)	0.026 (± 0.1818)		
Month 12 (n=120,108)	1.347 (± 0.1893)	1.271 (± 0.1798)		
Change at Month 12 (n=120,108)	-0.041 (± 0.1574)	-0.028 (± 0.1586)		
Month 18 (n=114,100)	1.339 (± 0.1972)	1.266 (± 0.1676)		
Change at Month 18 (n=114,100)	-0.049 (± 0.1558)	-0.038 (± 0.1643)		
Month 24 (n=113,95)	1.364 (± 0.1929)	1.275 (± 0.1736)		
Change at Month 24 (n=113,95)	-0.032 (± 0.1749)	-0.027 (± 0.1799)		
Month 30 (n=112,95)	1.357 (± 0.2247)	1.268 (± 0.1848)		
Change at Month 30 (n=112,95)	-0.04 (± 0.1857)	-0.036 (± 0.1861)		

Month 36/ET (n=125,118)	1.327 (± 0.2081)	1.272 (± 0.1664)		
Change at Month 36/ET (n=125,118)	-0.073 (± 0.1725)	-0.04 (± 0.1676)		

Statistical analyses

No statistical analyses for this end point

Primary: Percent Change from Baseline in Apolipoprotein (Apo A-1)

End point title	Percent Change from Baseline in Apolipoprotein (Apo A-1)[12]

End point description:

Assessments were performed in the fasting state (minimum 10-hour fast). FAS; n=number of subjects assessed for the specified parameter at a given visit.

End point type	Primary

End point timeframe:

Months 1, 2, 3, 6, 12, 18, 24, 30 and 36/ET

Notes:

[12] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Atorvastatin (5-80 mg): Tanner_Stage 1	Atorvastatin (10-80 mg): Tanner_Stage 2+		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	132	130		
Units: percent change				
arithmetic mean (standard deviation)				
Month 1 (n=132,130)	2.229 (± 12.4001)	3.301 (± 12.2009)		
Month 2 (n=131,123)	1.701 (± 11.0364)	2.499 (± 10.7656)		
Month 3 (n=126,117)	1.041 (± 12.4204)	1.192 (± 12.164)		
Month 6 (n=123,110)	-0.069 (± 12.1109)	3.011 (± 14.1347)		
Month 12 (n=120,108)	-2.365 (± 11.5882)	-1.37 (± 12.3901)		
Month 18 (n=114,100)	-3.042 (± 11.2219)	-1.98 (± 12.217)		
Month 24 (n=113,95)	-1.611 (± 12.4618)	-0.961 (± 13.9868)		
Month 30 (n=112,95)	-2.342 (± 13.3357)	-1.695 (± 14.2732)		
Month 36/ET (n=125,118)	-4.804 (± 12.0443)	-1.954 (± 12.7229)		

Statistical analyses

No statistical analyses for this end point

Primary: Apolipoprotein B (Apo B; g/L) During the Study

End point title	Apolipoprotein B (Apo B; g/L) During the Study[13]

End point description:

Assessments were performed in the fasting state (minimum 10-hour fast). Change from baseline was also determined. FAS; n=number of subjects assessed for the specified parameter at a given visit.

End point type	Primary

End point timeframe:

Baseline, Months 1, 2, 3, 6, 12, 18, 24, 30 and 36/ET

Notes:

[13] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Atorvastatin (5-80 mg): Tanner_Stage 1	Atorvastatin (10-80 mg): Tanner_Stage 2+		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	138	132		
Units: g/L				
arithmetic mean (standard deviation)				
Baseline (n=138,132)	1.454 (± 0.289)	1.381 (± 0.2619)		
Month 1 (n=132,130)	1.062 (± 0.2423)	0.967 (± 0.2257)		
Change at Month 1 (n=132,130)	-0.395 (± 0.1599)	-0.415 (± 0.1691)		
Month 2 (n=131,123)	0.98 (± 0.1929)	0.916 (± 0.1813)		
Change at Month 2 (n=131,123)	-0.471 (± 0.1825)	-0.484 (± 0.1858)		
Month 3 (n=126,117)	0.93 (± 0.1836)	0.89 (± 0.1707)		
Change at Month 3 (n=126,117)	-0.522 (± 0.2152)	-0.518 (± 0.2184)		
Month 6 (n=123,110)	0.919 (± 0.1557)	0.91 (± 0.1683)		
Change at Month 6 (n=123,110)	-0.535 (± 0.2092)	-0.503 (± 0.2086)		
Month 12 (n=120,108)	0.918 (± 0.1816)	0.871 (± 0.1493)		
Change at Month 12 (n=120,108)	-0.548 (± 0.2131)	-0.53 (± 0.2194)		
Month 18 (n=114,100)	0.893 (± 0.1546)	0.882 (± 0.1293)		
Change at Month 18 (n=114,100)	-0.578 (± 0.2343)	-0.533 (± 0.2463)		
Month 24 (n=113,95)	0.918 (± 0.1719)	0.884 (± 0.1575)		
Change at Month 24 (n=113,95)	-0.551 (± 0.2353)	-0.535 (± 0.2344)		
Month 30 (n=112,95)	0.91 (± 0.1723)	0.885 (± 0.1717)		
Change at Month 30 (n=112,95)	-0.56 (± 0.2664)	-0.533 (± 0.2467)		

Month 36/ET (n=125,118)	0.926 (± 0.186)	0.924 (± 0.2173)		
Change at Month 36/ET (n=125,118)	-0.52 (± 0.273)	-0.45 (± 0.2748)		

Statistical analyses

No statistical analyses for this end point

Primary: Percent Change from Baseline in Apolipoprotein B (Apo B)

End point title	Percent Change from Baseline in Apolipoprotein B (Apo B)[14]

End point description:

Assessments were performed in the fasting state (minimum 10-hour fast). FAS; n=number of subjects assessed for the specified parameter at a given visit.

End point type	Primary

End point timeframe:

Months 1, 2, 3, 6, 12, 18, 24, 30 and 36/ET

Notes:

[14] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Atorvastatin (5-80 mg): Tanner_Stage 1	Atorvastatin (10-80 mg): Tanner_Stage 2+		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	132	130		
Units: percent change				
arithmetic mean (standard deviation)				
Month 1 (n=132,130)	-26.933 (± 9.555)	-29.851 (± 10.3544)		
Month 2 (n=131,123)	-31.867 (± 9.2821)	-33.959 (± 9.9478)		
Month 3 (n=126,117)	-35.163 (± 10.568)	-35.849 (± 11.6832)		
Month 6 (n=123,110)	-35.9 (± 9.3398)	-34.74 (± 10.7982)		
Month 12 (n=120,108)	-36.624 (± 9.7413)	-36.842 (± 11.6106)		
Month 18 (n=114,100)	-38.158 (± 10.4084)	-36.211 (± 12.7805)		
Month 24 (n=113,95)	-36.426 (± 11.4333)	-36.677 (± 12.1824)		
Month 30 (n=112,95)	-36.668 (± 12.8783)	-36.453 (± 13.6888)		
Month 36/ET (n=125,118)	-34.507 (± 14.074)	-31.362 (± 16.477)		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects with Shift from Baseline in Tanner_Stage by Timepoint and Baseline Tanner_Stage

End point title	Number of Subjects with Shift from Baseline in Tanner_Stage by Timepoint and Baseline Tanner_Stage[15][16]

End point description:

Tanner_Stage was assessed based on 2 components by gender, pubic hair and breasts for females and pubic hair and genitalia for males. If these values of components were not same, then the Tanner_Stage had the higher value of 2 components for each gender by visit. FAS; n=number of subjects assessed for the specific parameter at a given visit.

End point type	Primary

End point timeframe:

Baseline, Months 6, 12, 18, 24, 30, and 36/ET

Notes:

[15] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was planned to be assessed for prespecified reporting groups of interest as Tanner Stage 2, 3, 4, 5 separately instead of Tanner_Stage 2+ (combined).

End point values	Atorvastatin (5-80 mg): Tanner_Stage 1	Atorvastatin (10-80 mg): Baseline Tanner_Stage 4	Atorvastatin (10-80 mg): Baseline Tanner_Stage 3	Atorvastatin (10-80 mg): Baseline Tanner_Stage 2
Subject group type	Reporting group	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	127	31	25	52
Units: subjects				
Tanner_Stage 1, Month 6 (n=126,48,25,27,15)	107	0	0	0
Tanner_Stage 2 , Month 6 (n=126,48,25,27,15)	14	0	0	34
Tanner_Stage 3, Month 6 (n=126,48,25,27,15)	5	0	14	10
Tanner_Stage 4, Month 6 (n=126,48,25,27,15)	0	25	11	4
Tanner_Stage 5, Month 6 (n=126,48,25,27,15)	0	2	0	0
Tanner_Stage 1, Month 12 (n=121,43,23,26,15)	85	0	0	0
Tanner_Stage 2, Month 12 (n=121,43,23,26,15)	25	0	0	17
Tanner_Stage 3, Month 12 (n=121,43,23,26,15)	10	0	11	21
Tanner_Stage 4, Month 12 (n=121,43,23,26,15)	1	22	10	5
Tanner_Stage 5, Month 12 (n=121,43,23,26,15)	0	4	2	0
Tanner_Stage 1, Month 18 (n=115,41, 21,25,14)	63	0	0	0
Tanner_Stage 2, Month 18 (n=115,41, 21,25,14)	31	0	0	15
Tanner_Stage 3, Month 18 (n=115,41, 21,25,14)	18	0	6	16

Tanner_Stage 4, Month 18 (n=115,41, 21,25,14)	3	18	11	9
Tanner_Stage 5, Month 18 (n=115,41, 21,25,14)	0	7	4	1
Tanner_Stage 1, Month 24 (n=113,38,19,22,14)	51	0	0	0
Tanner_Stage 2, Month 24 (n=113,38,19,22,14)	33	0	0	9
Tanner_Stage 3, Month 24 (n=113,38,19,22,14)	20	0	2	14
Tanner_Stage 4, Month 24 (n=113,38,19,22,14)	9	13	13	12
Tanner_Stage 5, Month 24 (n=113,38,19,22,14)	0	9	4	3
Tanner_Stage 1, Month 30 (n=111,38,19,23,14)	39	0	0	0
Tanner_Stage 2, Month 30 (n=111,38,19,23,14)	32	0	0	3
Tanner_Stage 3, Month 30 (n=111,38,19,23,14)	26	0	1	11
Tanner_Stage 4, Month 30 (n=111,38,19,23,14)	14	11	9	18
Tanner_Stage 5, Month 30 (n=111,38,19,23,14)	0	12	9	6
Tanner_Stage 1, Month 36/ET (n=127,52,25,31,18)	41	0	0	0
Tanner_Stage 2, Month 36/ET (n=127,52,25,31,18)	31	0	0	6
Tanner_Stage 3, Month 36/ET (n=127,52,25,31,18)	25	0	2	10
Tanner_Stage 4, Month 36/ET (n=127,52,25,31,18)	25	12	13	24
Tanner_Stage 5, Month 36/ET (n=127,52,25,31,18)	5	19	10	12

End point values	Atorvastatin (10-80 mg): Baseline Tanner_Stage 5			
Subject group type	Subject analysis set			
Number of subjects analysed	18			
Units: subjects				
Tanner_Stage 1, Month 6 (n=126,48,25,27,15)	0			
Tanner_Stage 2 , Month 6 (n=126,48,25,27,15)	0			
Tanner_Stage 3, Month 6 (n=126,48,25,27,15)	0			
Tanner_Stage 4, Month 6 (n=126,48,25,27,15)	1			
Tanner_Stage 5, Month 6 (n=126,48,25,27,15)	14			
Tanner_Stage 1, Month 12 (n=121,43,23,26,15)	0			
Tanner_Stage 2, Month 12 (n=121,43,23,26,15)	0			

Tanner_Stage 3, Month 12 (n=121,43,23,26,15)	0			
Tanner_Stage 4, Month 12 (n=121,43,23,26,15)	1			
Tanner_Stage 5, Month 12 (n=121,43,23,26,15)	14			
Tanner_Stage 1, Month 18 (n=115,41, 21,25,14)	0			
Tanner_Stage 2, Month 18 (n=115,41, 21,25,14)	0			
Tanner_Stage 3, Month 18 (n=115,41, 21,25,14)	0			
Tanner_Stage 4, Month 18 (n=115,41, 21,25,14)	1			
Tanner_Stage 5, Month 18 (n=115,41, 21,25,14)	13			
Tanner_Stage 1, Month 24 (n=113,38,19,22,14)	0			
Tanner_Stage 2, Month 24 (n=113,38,19,22,14)	0			
Tanner_Stage 3, Month 24 (n=113,38,19,22,14)	0			
Tanner_Stage 4, Month 24 (n=113,38,19,22,14)	1			
Tanner_Stage 5, Month 24 (n=113,38,19,22,14)	13			
Tanner_Stage 1, Month 30 (n=111,38,19,23,14)	0			
Tanner_Stage 2, Month 30 (n=111,38,19,23,14)	0			
Tanner_Stage 3, Month 30 (n=111,38,19,23,14)	0			
Tanner_Stage 4, Month 30 (n=111,38,19,23,14)	1			
Tanner_Stage 5, Month 30 (n=111,38,19,23,14)	13			
Tanner_Stage 1, Month 36/ET (n=127,52,25,31,18)	0			
Tanner_Stage 2, Month 36/ET (n=127,52,25,31,18)	0			
Tanner_Stage 3, Month 36/ET (n=127,52,25,31,18)	0			
Tanner_Stage 4, Month 36/ET (n=127,52,25,31,18)	0			
Tanner_Stage 5, Month 36/ET (n=127,52,25,31,18)	18			

Statistical analyses

No statistical analyses for this end point

Primary: Height (centimeters [cm]) During the Study: Males

End point title	Height (centimeters [cm]) During the Study: Males[17]

End point description:

Investigator assessment of height changes during the study. Change from baseline was also determined. FAS; only male subjects were included in the analysis. n=number of subjects assessed for the specified parameter at a given visit.

End point type	Primary

End point timeframe:

Baseline, Months 1, 2, 3, 6, 12, 18, 24, 30 and 36/ET

Notes:

[17] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Atorvastatin (5-80 mg)			
Subject group type	Subject analysis set			
Number of subjects analysed	146			
Units: cm				
arithmetic mean (standard deviation)				
Baseline (n=146)	144.36 (± 16.004)			
Month 1 (n=141)	145.21 (± 16.114)			
Change at Month 1 (n=141)	0.68 (± 0.964)			
Month 2 (n=138)	145.93 (± 16.302)			
Change at Month 2 (n=138)	1.27 (± 0.964)			
Month 3 (n=133)	146 (± 16.139)			
Change at Month 3 (n=133)	1.72 (± 1.172)			
Month 6 (n=129)	147.17 (± 16.033)			
Change at Month 6 (n=129)	3.24 (± 1.485)			
Month 12 (n=123)	150.75 (± 16.321)			
Change at Month 12 (n=123)	6.67 (± 2.385)			
Month 18 (n=119)	153.26 (± 16.388)			
Change at Month 18 (n=119)	9.31 (± 2.978)			
Month 24 (n=114)	156.03 (± 16.001)			
Change at Month 24 (n=114)	12.11 (± 3.63)			
Month 30 (n=114)	158.78 (± 15.77)			
Change at Month 30 (n=114)	14.86 (± 4.403)			
Month 36/ET (n=134)	160.59 (± 15.602)			
Change at Month 36/ET (n=134)	15.53 (± 6.801)			

Statistical analyses

No statistical analyses for this end point

Primary: Percent Change from Baseline in Height: Males

End point title	Percent Change from Baseline in Height: Males[18]

End point description:

Investigator assessment of height changes during the study. FAS; only male subjects were included in the analysis. n=number of subjects assessed for the specified parameter at a given visit.

End point type	Primary

End point timeframe:

Months 1, 2, 3, 6, 12, 18, 24, 30 and 36/ET

Notes:

[18] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Atorvastatin (5-80 mg)			
Subject group type	Subject analysis set			
Number of subjects analysed	141			
Units: percent change				
arithmetic mean (standard deviation)				
Month 1 (n=141)	0.47 (± 0.689)			
Month 2 (n=138)	0.88 (± 0.652)			
Month 3 (n=133)	1.19 (± 0.777)			
Month 6 (n=129)	2.25 (± 0.987)			
Month 12 (n=123)	4.66 (± 1.606)			
Month 18 (n=119)	6.53 (± 2.021)			
Month 24 (n=114)	8.53 (± 2.607)			
Month 30 (n=114)	10.49 (± 3.26)			
Month 36/ET (n=134)	10.97 (± 5.01)			

Statistical analyses

No statistical analyses for this end point

Primary: Height (cm) During the Study: Females

End point title	Height (cm) During the Study: Females[19]

End point description:

Investigator assessment of height changes during the study. Change from baseline was also determined. FAS; only female subjects were included in the analysis. n=number of subjects assessed for the specified parameter at a given visit.

End point type	Primary

End point timeframe:

Baseline, Months 1, 2, 3, 6, 12, 18, 24, 30 and 36/ET

Notes:

[19] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Atorvastatin (5-80 mg)			
Subject group type	Subject analysis set			
Number of subjects analysed	125			
Units: cm				
arithmetic mean (standard deviation)				
Baseline (n=125)	145.28 (± 14.108)			

Month 1 (n=124)	146.06 (± 14.045)			
Change at Month 1 (n=124)	0.71 (± 1.378)			
Month 2 (n=119)	146.57 (± 13.919)			
Change at Month 2 (n=119)	1.19 (± 1.7)			
Month 3 (n=115)	146.81 (± 13.838)			
Change at Month 3 (n=115)	1.68 (± 1.278)			
Month 6 (n=113)	147.87 (± 13.619)			
Change at Month 6 (n=113)	2.77 (± 1.72)			
Month 12 (n=107)	150.84 (± 12.968)			
Change at Month 12 (n=107)	5.5 (± 2.992)			
Month 18 (n=99)	152.77 (± 12.648)			
Change at Month 18 (n=99)	7.41 (± 4.043)			
Month 24 (n=95)	154.79 (± 11.913)			
Change at Month 24 (n=95)	9.61 (± 5.12)			
Month 30 (n=93)	156.43 (± 11.288)			
Change at Month 30 (n=93)	11.23 (± 6.118)			
Month 36/ET (n=121)	156.52 (± 11.032)			
Change at Month 36/ET (n=121)	11.23 (± 7.551)			

Statistical analyses

No statistical analyses for this end point

Primary: Percent Change from Baseline in Height: Females

End point title	Percent Change from Baseline in Height: Females[20]

End point description:

Investigator assessment of height changes during the study. FAS; only female subjects were included in the analysis. n=number of subjects assessed for the specified parameter at a given visit.

End point type	Primary

End point timeframe:

Months 1, 2, 3, 6, 12, 18, 24, 30 and 36/ET

Notes:

[20] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Atorvastatin (5-80 mg)			
Subject group type	Subject analysis set			
Number of subjects analysed	124			
Units: percent change				
arithmetic mean (standard deviation)				
Month 1 (n=124)	0.51 (± 1.004)			
Month 2 (n=119)	0.84 (± 1.22)			
Month 3 (n=115)	1.2 (± 0.925)			
Month 6 (n=113)	1.98 (± 1.291)			
Month 12 (n=107)	3.93 (± 2.262)			
Month 18 (n=99)	5.3 (± 3.036)			
Month 24 (n=95)	6.93 (± 3.933)			
Month 30 (n=93)	8.13 (± 4.74)			
Month 36/ET (n=121)	8.14 (± 5.789)			

Statistical analyses

No statistical analyses for this end point

Primary: Weight (kilograms [kg]) During the Study: Males

End point title	Weight (kilograms [kg]) During the Study: Males[21]

End point description:

Investigator assessment of weight changes during the study. Change from baseline was also determined. FAS; only male subjects were included in the analysis. n=number of subjects assessed for the specified parameter at a given visit.

End point type	Primary

End point timeframe:

Baseline, Months 1, 2, 3, 6, 12, 18, 24, 30 and 36/ET

Notes:

[21] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Atorvastatin (5-80 mg)			
Subject group type	Subject analysis set			
Number of subjects analysed	146			
Units: kg				
arithmetic mean (standard deviation)				
Baseline (n=146)	40.79 (± 14.079)			
Month 1 (n=141)	41.18 (± 14.287)			
Change at Month 1 (n=141)	0.36 (± 1.203)			
Month 2 (n=138)	41.83 (± 14.467)			
Change at Month 2 (n=138)	0.8 (± 1.422)			
Month 3 (n=133)	41.68 (± 14.266)			
Change at Month 3 (n=133)	1.08 (± 1.907)			

Month 6 (n=129)	42.47 (± 14.564)			
Change at Month 6 (n=129)	2 (± 2.528)			
Month 12 (n=123)	45.29 (± 15.526)			
Change at Month 12 (n=123)	4.65 (± 3.822)			
Month 18 (n=119)	47.53 (± 16.164)			
Change at Month 18 (n=119)	7.02 (± 4.432)			
Month 24 (n=114)	49.77 (± 16.401)			
Change at Month 24 (n=114)	9.27 (± 5.079)			
Month 30 (n=114)	52.12 (± 17.1)			
Change at Month 30 (n=114)	11.61 (± 6.032)			
Month 36/ET (n=134)	53.5 (± 16.787)			
Change at Month 36/ET (n=134)	12.35 (± 6.771)			

Statistical analyses

No statistical analyses for this end point

Primary: Percent Change from Baseline in Weight: Males

End point title	Percent Change from Baseline in Weight: Males[22]

End point description:

Investigator assessment of weight changes during the study. FAS; only male subjects were included in the analysis. n=number of subjects assessed for the specified parameter at a given visit.

End point type	Primary

End point timeframe:

Months 1, 2, 3, 6, 12, 18, 24, 30 and 36/ET

Notes:

[22] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Atorvastatin (5-80 mg)			
Subject group type	Subject analysis set			
Number of subjects analysed	141			
Units: percent change				
arithmetic mean (standard deviation)				
Month 1 (n=141)	0.94 (± 2.739)			
Month 2 (n=138)	2.04 (± 3.262)			
Month 3 (n=133)	2.73 (± 4.317)			
Month 6 (n=129)	5.09 (± 5.559)			
Month 12 (n=123)	11.85 (± 8.172)			
Month 18 (n=119)	18.03 (± 9.629)			
Month 24 (n=114)	24.28 (± 11.696)			

Month 30 (n=114)	30.46 (± 14.058)			
Month 36/ET (n=134)	32.54 (± 17.409)			

Statistical analyses

No statistical analyses for this end point

Primary: Weight (kg) During the Study: Females

End point title	Weight (kg) During the Study: Females[23]

End point description:

Investigator assessment of weight changes during the study. Change from baseline was also determined. FAS; only female subjects were included in the analysis. n=number of subjects assessed for the specified parameter at a given visit.

End point type	Primary

End point timeframe:

Baseline, Months 1, 2, 3, 6, 12, 18, 24, 30 and 36/ET

Notes:

[23] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Atorvastatin (5-80 mg)			
Subject group type	Subject analysis set			
Number of subjects analysed	125			
Units: kg				
arithmetic mean (standard deviation)				
Baseline (n=125)	42.14 (± 14.038)			
Month 1 (n=125)	42.5 (± 14.007)			
Change at Month 1 (n=125)	0.36 (± 0.924)			
Month 2 (n=120)	42.86 (± 14.209)			
Change at Month 2 (n=120)	0.67 (± 1.338)			
Month 3 (n=115)	43.34 (± 14.753)			
Change at Month 3 (n=115)	1.24 (± 1.819)			
Month 6 (n=113)	44.26 (± 15.027)			
Change at Month 6 (n=113)	2.1 (± 2.409)			
Month 12 (n=107)	46.61 (± 15.158)			
Change at Month 12 (n=107)	4.41 (± 3.317)			
Month 18 (n=99)	48.32 (± 14.67)			
Change at Month 18 (n=99)	6.24 (± 4.291)			
Month 24 (n=95)	50.13 (± 14.731)			
Change at Month 24 (n=95)	8.55 (± 5.038)			

Month 30 (n=93)	51.73 (± 14.681)			
Change at Month 30 (n=93)	10.02 (± 6.127)			
Month 36/ET (n=121)	51.55 (± 14.498)			
Change at Month 36/ET (n=121)	9.77 (± 7.047)			

Statistical analyses

No statistical analyses for this end point

Primary: Percent Change from Baseline in Weight: Females

End point title	Percent Change from Baseline in Weight: Females[24]

End point description:

Investigator assessment of weight changes during the study. FAS; only female subjects were included in the analysis. n=number of subjects assessed for the specified parameter at a given visit.

End point type	Primary

End point timeframe:

Months 1, 2, 3, 6, 12, 18, 24, 30 and 36/ET

Notes:

[24] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Atorvastatin (5-80 mg)			
Subject group type	Subject analysis set			
Number of subjects analysed	125			
Units: percent change				
arithmetic mean (standard deviation)				
Month 1 (n=125)	0.97 (± 2.303)			
Month 2 (n=120)	1.85 (± 3.206)			
Month 3 (n=115)	3.16 (± 4.149)			
Month 6 (n=113)	5.37 (± 5.529)			
Month 12 (n=107)	11.65 (± 8.391)			
Month 18 (n=99)	16.79 (± 11.315)			
Month 24 (n=95)	23.43 (± 14.333)			
Month 30 (n=93)	27.83 (± 17.507)			
Month 36/ET (n=121)	27.26 (± 21.389)			

Statistical analyses

No statistical analyses for this end point

Primary: Body Mass Index (BMI in kg per square meter [kg/m^2]) During the Study: Males

End point title	Body Mass Index (BMI in kg per square meter [kg/m^2]) During the Study: Males[25]

End point description:

Investigator assessment of BMI changes during the study. Change from baseline was also determined. FAS; only male subjects were included in the analysis. n=number of subjects assessed for the specified parameter at a given visit.

End point type	Primary

End point timeframe:

Baseline, Months 1, 2, 3, 6, 12, 18, 24, 30 and 36/ET

Notes:

[25] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Atorvastatin (5-80 mg)			
Subject group type	Subject analysis set			
Number of subjects analysed	146			
Units: kg/m^2				
arithmetic mean (standard deviation)				
Baseline (n=146)	18.97 (± 3.664)			
Month 1 (n=141)	18.94 (± 3.751)			
Change at Month 1 (n=141)	0.01 (± 0.577)			
Month 2 (n=138)	19.06 (± 3.755)			
Change at Month 2 (n=138)	0.06 (± 0.658)			
Month 3 (n=133)	18.99 (± 3.745)			
Change at Month 3 (n=133)	0.07 (± 0.89)			
Month 6 (n=129)	19.04 (± 3.881)			
Change at Month 6 (n=129)	0.1 (± 1.218)			
Month 12 (n=123)	19.34 (± 3.922)			
Change at Month 12 (n=123)	0.37 (± 1.541)			
Month 18 (n=119)	19.65 (± 4.053)			
Change at Month 18 (n=119)	0.73 (± 1.625)			
Month 24 (n=114)	19.91 (± 4.098)			
Change at Month 24 (n=114)	0.99 (± 1.745)			
Month 30 (n=114)	20.18 (± 4.4)			
Change at Month 30 (n=114)	1.25 (± 2.099)			
Month 36/ET (n=134)	20.28 (± 4.137)			
Change at Month 36/ET (n=134)	1.33 (± 1.958)			

Statistical analyses

No statistical analyses for this end point

Primary: Percent Change from Baseline in BMI: Males

End point title	Percent Change from Baseline in BMI: Males[26]

End point description:

Investigator assessment of BMI changes during the study. FAS; only male subjects were included in the analysis. n=number of subjects assessed for the specified parameter at a given visit.

End point type	Primary

End point timeframe:

Months 1, 2, 3, 6, 12, 18, 24, 30 and 36/ET

Notes:

[26] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Atorvastatin (5-80 mg)			
Subject group type	Subject analysis set			
Number of subjects analysed	141			
Units: percent change				
arithmetic mean (standard deviation)				
Month 1 (n=141)	0.03 (± 2.953)			
Month 2 (n=138)	0.31 (± 3.405)			
Month 3 (n=133)	0.39 (± 4.496)			
Month 6 (n=129)	0.55 (± 5.673)			
Month 12 (n=123)	2.1 (± 7.065)			
Month 18 (n=119)	3.98 (± 7.533)			
Month 24 (n=114)	5.45 (± 8.306)			
Month 30 (n=114)	6.8 (± 9.737)			
Month 36/ET (n=134)	7.31 (± 9.29)			

Statistical analyses

No statistical analyses for this end point

Primary: BMI (kg/m^2) During the Study: Females

End point title	BMI (kg/m^2) During the Study: Females[27]

End point description:

Investigator assessment of BMI changes during the study. Change from baseline was also determined. FAS; only female subjects were included in the analysis. n=number of subjects assessed for the specified parameter at a given visit.

End point type	Primary

End point timeframe:

Baseline, Months 1, 2, 3, 6, 12, 18, 24, 30 and 36/ET

Notes:

[27] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Atorvastatin (5-80 mg)			
Subject group type	Subject analysis set			
Number of subjects analysed	125			
Units: kg/m^2				
arithmetic mean (standard deviation)				
Baseline (n=125)	19.44 (± 3.994)			
Month 1 (n=124)	19.45 (± 3.973)			
Change at Month 1 (n=124)	-0.02 (± 0.582)			
Month 2 (n=119)	19.47 (± 3.94)			
Change at Month 2 (n=119)	0 (± 0.756)			
Month 3 (n=115)	19.54 (± 4.171)			
Change at Month 3 (n=115)	0.13 (± 0.861)			
Month 6 (n=113)	19.68 (± 4.288)			
Change at Month 6 (n=113)	0.24 (± 1.004)			
Month 12 (n=107)	19.98 (± 4.257)			
Change at Month 12 (n=107)	0.6 (± 1.305)			
Month 18 (n=99)	20.24 (± 3.99)			
Change at Month 18 (n=99)	0.92 (± 1.432)			
Month 24 (n=95)	20.5 (± 3.976)			
Change at Month 24 (n=95)	1.38 (± 1.624)			
Month 30 (n=93)	20.75 (± 4.014)			
Change at Month 30 (n=93)	1.59 (± 1.931)			
Month 36/ET (n=121)	20.71 (± 4.217)			
Change at Month 36/ET (n=121)	1.46 (± 1.948)			

Statistical analyses

No statistical analyses for this end point

Primary: Percent Change from Baseline in BMI: Females

End point title	Percent Change from Baseline in BMI: Females[28]

End point description:

Investigator assessment of BMI changes during the study. FAS; only female subjects were included in the analysis. n=number of subjects assessed for the specified parameter at a given visit.

End point type	Primary

End point timeframe:

Months 1, 2, 3, 6, 12, 18, 24, 30 and 36/ET

Notes:

[28] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Atorvastatin (5-80 mg)			
Subject group type	Subject analysis set			
Number of subjects analysed	124			
Units: percent change				
arithmetic mean (standard deviation)				
Month 1 (n=124)	-0.06 (± 3.058)			
Month 2 (n=119)	0.16 (± 3.777)			
Month 3 (n=115)	0.73 (± 4.314)			
Month 6 (n=113)	1.26 (± 4.992)			
Month 12 (n=107)	3.33 (± 6.765)			
Month 18 (n=99)	5.14 (± 7.578)			
Month 24 (n=95)	7.68 (± 8.661)			
Month 30 (n=93)	8.89 (± 9.916)			
Month 36/ET (n=121)	8.06 (± 10.147)			

Statistical analyses

No statistical analyses for this end point

Primary: Age (years) During the Study: Males

End point title	Age (years) During the Study: Males[29]

End point description:

Investigator assessment of age during the study. Change from baseline was also determined. FAS; only male subjects were included in the analysis. n=number of subjects assessed for the specified parameter at a given visit.

End point type	Primary

End point timeframe:

Baseline, Months 1, 2, 3, 6, 12, 18, 24, 30 and 36/ET

Notes:

[29] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Atorvastatin (5-80 mg)			
Subject group type	Subject analysis set			
Number of subjects analysed	146			
Units: years				
arithmetic mean (standard deviation)				
Baseline (n=146)	9.94 (± 2.489)			
Month 1 (n=141)	10.05 (± 2.553)			
Change at Month 1 (n=141)	0.11 (± 0.309)			
Month 2 (n=138)	10.14 (± 2.583)			
Change at Month 2 (n=138)	0.18 (± 0.387)			
Month 3 (n=133)	10.21 (± 2.567)			
Change at Month 3 (n=133)	0.29 (± 0.457)			

Month 6 (n=129)	10.43 (± 2.552)			
Change at Month 6 (n=129)	0.55 (± 0.499)			
Month 12 (n=123)	10.96 (± 2.543)			
Change at Month 12 (n=123)	1.02 (± 0.155)			
Month 18 (n=119)	11.47 (± 2.544)			
Change at Month 18 (n=119)	1.54 (± 0.501)			
Month 24 (n=114)	11.93 (± 2.534)			
Change at Month 24 (n=114)	2.02 (± 0.132)			
Month 30 (n=114)	12.46 (± 2.553)			
Change at Month 30 (n=114)	2.54 (± 0.5)			
Month 36/ET (n=134)	12.69 (± 2.587)			
Change at Month 36/ET (n=134)	2.67 (± 0.899)			

Statistical analyses

No statistical analyses for this end point

Primary: Percent Change from Baseline in Age: Males

End point title	Percent Change from Baseline in Age: Males[30]

End point description:

Investigator assessment of age during the study. FAS; only male subjects were included in the analysis. n=number of subjects assessed for the specified parameter at a given visit.

End point type	Primary

End point timeframe:

Months 1, 2, 3, 6, 12, 18, 24, 30 and 36/ET

Notes:

[30] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Atorvastatin (5-80 mg)			
Subject group type	Subject analysis set			
Number of subjects analysed	141			
Units: percent change				
arithmetic mean (standard deviation)				
Month 1 (n=141)	1.09 (± 3.327)			
Month 2 (n=138)	1.86 (± 4.184)			
Month 3 (n=133)	3.16 (± 5.175)			
Month 6 (n=129)	6.06 (± 5.956)			
Month 12 (n=123)	11.13 (± 3.878)			
Month 18 (n=119)	16.82 (± 7.732)			
Month 24 (n=114)	21.92 (± 6.623)			

Month 30 (n=114)	27.67 (± 9.855)			
Month 36/ET (n=134)	28.9 (± 13.486)			

Statistical analyses

No statistical analyses for this end point

Primary: Age (years) During the Study: Females

End point title	Age (years) During the Study: Females[31]

End point description:

Investigator assessment of age during the study. Change from baseline was also determined. FAS; only female subjects were included in the analysis. n=number of subjects assessed for the specified parameter at a given visit.

End point type	Primary

End point timeframe:

Baseline, Months 1, 2, 3, 6, 12, 18, 24, 30 and 36/ET

Notes:

[31] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Atorvastatin (5-80 mg)			
Subject group type	Subject analysis set			
Number of subjects analysed	125			
Units: years				
arithmetic mean (standard deviation)				
Baseline (n=125)	10.55 (± 2.421)			
Month 1 (n=125)	10.66 (± 2.436)			
Change at Month 1 (n=125)	0.11 (± 0.317)			
Month 2 (n=120)	10.78 (± 2.43)			
Change at Month 2 (n=120)	0.2 (± 0.402)			
Month 3 (n=115)	10.75 (± 2.449)			
Change at Month 3 (n=115)	0.28 (± 0.45)			
Month 6 (n=113)	10.99 (± 2.477)			
Change at Month 6 (n=113)	0.52 (± 0.502)			
Month 12 (n=107)	11.5 (± 2.416)			
Change at Month 12 (n=107)	0.99 (± 0.097)			
Month 18 (n=99)	12.02 (± 2.503)			
Change at Month 18 (n=99)	1.52 (± 0.502)			
Month 24 (n=95)	12.42 (± 2.482)			
Change at Month 24 (n=95)	1.98 (± 0.144)			
Month 30 (n=93)	12.99 (± 2.564)			
Change at Month 30 (n=93)	2.52 (± 0.502)			

Month 36/ET (n=121)	13.07 (± 2.547)			
Change at Month 36/ET (n=121)	2.54 (± 0.94)			

Statistical analyses

No statistical analyses for this end point

Primary: Percent Change from Baseline in Age: Females

End point title	Percent Change from Baseline in Age: Females[32]

End point description:

Investigator assessment of age during the study. FAS; only female subjects were included in the analysis. n=number of subjects assessed for the specified parameter at a given visit.

End point type	Primary

End point timeframe:

Months 1, 2, 3, 6, 12, 18, 24, 30 and 36/ET

Notes:

[32] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Atorvastatin (5-80 mg)			
Subject group type	Subject analysis set			
Number of subjects analysed	125			
Units: percent change				
arithmetic mean (standard deviation)				
Month 1 (n=125)	1.1 (± 3.169)			
Month 2 (n=120)	2 (± 4.128)			
Month 3 (n=115)	2.74 (± 4.549)			
Month 6 (n=113)	5.18 (± 5.221)			
Month 12 (n=107)	10 (± 2.811)			
Month 18 (n=99)	15.2 (± 6.006)			
Month 24 (n=95)	20.08 (± 5.298)			
Month 30 (n=93)	25.35 (± 7.415)			
Month 36/ET (n=121)	25.73 (± 12.168)			

Statistical analyses

No statistical analyses for this end point

Primary: Flow-Mediated Dilatation (FMD) During the Study

End point title	Flow-Mediated Dilatation (FMD) During the Study[33]

End point description:

Percent (%) FMD was calculated as (hyperemic diameter minus resting diameter) divided by the resting

diameter multiplied by 100. Change from baseline was also determined. FMD Set: all subjects enrolled in the FMD study who had at least baseline FMD measurements. n=number of subjects assessed for the specified parameter at a given visit.

End point type	Primary

End point timeframe:

Baseline, Months 6, 12, 18, 24, 30 and 36/ET

Notes:

[33] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Atorvastatin (5-80 mg): Tanner_Stage 1	Atorvastatin (10-80 mg): Tanner_Stage 2+		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37	36		
Units: % FMD				
arithmetic mean (standard deviation)				
Baseline (n=37,36)	5.523 (± 3.2062)	6.651 (± 4.4926)		
Month 6 (n=27,23)	5.749 (± 2.5047)	6.52 (± 4.0763)		
Change at Month 6 (n=27,23)	-0.063 (± 3.4768)	-0.759 (± 4.8732)		
Month 12 (n=32,29)	4.732 (± 1.8477)	6.363 (± 8.037)		
Change at Month 12 (n=32,29)	-0.952 (± 3.6796)	-0.778 (± 9.4743)		
Month 18 (n=33,28)	4.942 (± 2.674)	4.668 (± 3.8874)		
Change at Month 18 (n=33,28)	-0.762 (± 3.7374)	-2.556 (± 6.3123)		
Month 24 (n=33,28)	4.538 (± 2.4239)	5.679 (± 4.3224)		
Change at Month 24 (n=33,28)	-1.166 (± 3.2524)	-1.545 (± 7.2325)		
Month 30 (n=33,28)	5.571 (± 2.7198)	5.191 (± 2.512)		
Change at Month 30 (n=33,28)	-0.134 (± 3.3399)	-2.033 (± 5.8591)		
Month 36/ET (n=34,33)	4.987 (± 2.254)	5.36 (± 2.9873)		
Change at Month 36/ET (n=34,33)	-0.55 (± 3.6625)	-1.563 (± 4.8355)		

Statistical analyses

No statistical analyses for this end point

Primary: Percent Change from Baseline in FMD

End point title	Percent Change from Baseline in FMD[34]

End point description:

Percent (%) FMD was calculated as (hyperemic diameter minus resting diameter) divided by the resting diameter multiplied by 100. FMD Set; n=number of subjects assessed for the specified parameter at a

given visit.

End point type	Primary

End point timeframe:

Months 6, 12, 18, 24, 30 and 36/ET

Notes:

[34] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Atorvastatin (5-80 mg): Tanner_Stage 1	Atorvastatin (10-80 mg): Tanner_Stage 2+		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	34	33		
Units: percent change				
arithmetic mean (standard deviation)				
Month 6 (n=27,23)	14.867 (± 67.6028)	-0.205 (± 60.7192)		
Month 12 (n=32,29)	-3.88 (± 56.191)	15.444 (± 207.6932)		
Month 18 (n=33,28)	-4.598 (± 68.0267)	-24.387 (± 81.5683)		
Month 24 (n=33,28)	-9.992 (± 57.3868)	3.85 (± 102.2001)		
Month 30 (n=33,28)	7 (± 63.0894)	-18.804 (± 42.2259)		
Month 36/ET (n=34,33)	0.648 (± 62.5814)	-7.506 (± 61.2361)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Overall Expected Maturation and Development Consistent with Expectations as Assessed by the Investigator

End point title	Percentage of Subjects With Overall Expected Maturation and Development Consistent with Expectations as Assessed by the Investigator

End point description:

FAS; n=number of subjects assessed for the specified parameter at a given visit.

End point type	Secondary

End point timeframe:

Baseline, Months 1, 2, 3, 6, 12, 18, 24, 30 and 36 (or early termination)

End point values	Atorvastatin (5-80 mg): Tanner_Stage 1	Atorvastatin (10-80 mg): Tanner_Stage 2+		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	139	132		
Units: Percentage of subjects				
number (not applicable)				
Baseline (n=139,132)	99.3	100		
Month 1 (n=118,113)	100	100		
Month 2 (n=116,109)	100	100		
Month 3 (n=130,118)	100	100		
Month 6 (n=127,115)	100	99.1		
Month 12 (n=121,109)	100	99.1		
Month 18 (n=115,102)	100	100		
Month 24 (n=113,95)	100	100		
Month 30 (n=111,94)	100	98.9		
Month 36/Early Termination (n=128,127)	99.2	99.2		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects by Study Drug Compliance Category

End point title	Percentage of subjects by Study Drug Compliance Category

End point description:

Compliance to study drug was categorized as <80%, 80% - 120%, and greater than (>) 120%. Safety Analysis Set: all subjects who received at least 1 dose of study drug; n=number of subjects assessed for the specified parameter at a given visit.

End point type	Secondary

End point timeframe:

Months 1, 2, 3, 6, 12, 18, 24, 30, and 36 (or early termination)

End point values	Atorvastatin (5-80 mg): Tanner_Stage 1	Atorvastatin (10-80 mg): Tanner_Stage 2+		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	135	132		
Units: percentage of subjects				
number (not applicable)				
Month 1, <80% (n=135,132)	3	6.8		
Month 1, 80%-120% (n=135,132)	97	93.2		
Month 1, >120% (n=135,132)	0	0		
Month 2, <80% (n=132,126)	6.8	7.9		
Month 2, 80%-120% (n=132,126)	92.4	92.1		
Month 2, >120% (n=132,126)	0.8	0		

Month 3, <80% (n=130,118)	3.8	7.6		
Month 3, 80%-120% (n=130,118)	95.4	92.4		
Month 3, >120% (n=130,118)	0.8	0		
Month 6, <80% (n=127,115)	7.9	9.6		
Month 6, 80%-120% (n=127,115)	92.1	90.4		
Month 6, >120% (n=127,115)	0	0		
Month 12, <80% (n=121,109)	7.4	7.3		
Month 12, 80%-120% (n=121,109)	92.6	92.7		
Month 12, >120% (n=121,109)	0	0		
Month 18, <80% (n=116,102)	4.3	5.9		
Month 18, 80%-120% (n=116,102)	94	94.1		
Month 18, >120% (n=116,102)	1.7	0		
Month 24, <80% (n=113,95)	8.8	9.5		
Month 24, 80%-120% (n=113,95)	91.2	89.5		
Month 24, >120% (n=113,95)	0	1.1		
Month 30, <80% (n=112,94)	8	6.4		
Month 30, 80%-120% (n=112,94)	92	92.6		
Month 30, >120% (n=112,94)	0	1.1		
Month 36/ET, <80% (n=129,129)	11.6	16.3		
Month 36/ET, 80%-120% (n=129,129)	86.8	83.7		
Month 36/ET, >120% (n=129,129)	1.6	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline up through Month 36

Adverse event reporting additional description:

The same event may appear as both an adverse event (AE) and a serious AE (SAE). However, what is presented are distinct events. An event may be categorized as serious in 1 subject and as nonserious in another subject, or one subject may have experienced both a serious and nonserious event during the study.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17.0

Reporting groups

Reporting group title	Atorvastatin (10-80 mg): Tanner_Stage 2+

Reporting group description:

Subjects aged ≥10 to 15 years, at Tanner_Stage 2+ received an initial dose of atorvastatin tablets, 10mg/day, PO, through Week 4; after Week 4, dose may have been doubled to 20 mg/day, with subsequent doubling to 40 mg/day (as necessary; maximum dose was 80 mg/day), PO, if target LDL-C (<3.35 mmol/L) was not attained.

Reporting group title	Atorvastatin (5-80 mg): Tanner_Stage 1

Reporting group description:

Subjects aged 6 to <10 years, at Tanner_Stage 1 received an initial dose of atorvastatin tablets, 5 mg/day, PO, through Week 4; after Week 4, dose may have been doubled to 10 mg/day, with subsequent doubling to 20 mg/day (as necessary; maximum dose was 80 mg/day), PO, if target LDL-C (<3.35 mmol/L) was not attained.

Serious adverse events	Atorvastatin (10-80 mg): Tanner_Stage 2+	Atorvastatin (5-80 mg): Tanner_Stage 1	
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 132 (5.30%)	14 / 139 (10.07%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Ewing's sarcoma			
subjects affected / exposed	0 / 132 (0.00%)	1 / 139 (0.72%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intravascular papillary endothelial hyperplasia			
subjects affected / exposed	0 / 132 (0.00%)	1 / 139 (0.72%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Injury, poisoning and procedural complications			
Concussion			
subjects affected / exposed	0 / 132 (0.00%)	1 / 139 (0.72%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb injury			
subjects affected / exposed	1 / 132 (0.76%)	0 / 139 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar vertebral fracture			
subjects affected / exposed	1 / 132 (0.76%)	0 / 139 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thoracic vertebral fracture			
subjects affected / exposed	1 / 132 (0.76%)	0 / 139 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulna fracture			
subjects affected / exposed	0 / 132 (0.00%)	1 / 139 (0.72%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Syncope			
subjects affected / exposed	1 / 132 (0.76%)	1 / 139 (0.72%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Feeling abnormal			
subjects affected / exposed	0 / 132 (0.00%)	1 / 139 (0.72%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain			

subjects affected / exposed	1 / 132 (0.76%)	1 / 139 (0.72%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendix disorder			
subjects affected / exposed	0 / 132 (0.00%)	1 / 139 (0.72%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoids			
subjects affected / exposed	0 / 132 (0.00%)	1 / 139 (0.72%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	1 / 132 (0.76%)	0 / 139 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Testicular appendage torsion			
subjects affected / exposed	0 / 132 (0.00%)	1 / 139 (0.72%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Bipolar disorder			
subjects affected / exposed	0 / 132 (0.00%)	1 / 139 (0.72%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide attempt			
subjects affected / exposed	1 / 132 (0.76%)	0 / 139 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Myositis			

subjects affected / exposed	0 / 132 (0.00%)	1 / 139 (0.72%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 132 (0.00%)	2 / 139 (1.44%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	0 / 132 (0.00%)	1 / 139 (0.72%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Obesity			
subjects affected / exposed	1 / 132 (0.76%)	0 / 139 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 1 diabetes mellitus			
subjects affected / exposed	1 / 132 (0.76%)	0 / 139 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Atorvastatin (10-80 mg): Tanner_Stage 2+	Atorvastatin (5-80 mg): Tanner_Stage 1	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	86 / 132 (65.15%)	93 / 139 (66.91%)	
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	9 / 132 (6.82%)	3 / 139 (2.16%)	
occurrences (all)	10	3	
Nervous system disorders			
Headache			

subjects affected / exposed	25 / 132 (18.94%)	25 / 139 (17.99%)	
occurrences (all)	53	41	
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	13 / 132 (9.85%)	15 / 139 (10.79%)	
occurrences (all)	20	21	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	10 / 132 (7.58%)	21 / 139 (15.11%)	
occurrences (all)	13	23	
Abdominal pain upper			
subjects affected / exposed	3 / 132 (2.27%)	7 / 139 (5.04%)	
occurrences (all)	3	10	
Diarrhoea			
subjects affected / exposed	9 / 132 (6.82%)	8 / 139 (5.76%)	
occurrences (all)	10	9	
Nausea			
subjects affected / exposed	8 / 132 (6.06%)	3 / 139 (2.16%)	
occurrences (all)	13	8	
Vomiting			
subjects affected / exposed	7 / 132 (5.30%)	15 / 139 (10.79%)	
occurrences (all)	11	17	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	11 / 132 (8.33%)	14 / 139 (10.07%)	
occurrences (all)	18	28	
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	10 / 132 (7.58%)	4 / 139 (2.88%)	
occurrences (all)	10	4	
Pain in extremity			
subjects affected / exposed	5 / 132 (3.79%)	14 / 139 (10.07%)	
occurrences (all)	5	26	
Arthralgia			

subjects affected / exposed	5 / 132 (3.79%)	10 / 139 (7.19%)	
occurrences (all)	8	15	
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 132 (0.76%)	9 / 139 (6.47%)	
occurrences (all)	1	11	
Ear infection			
subjects affected / exposed	6 / 132 (4.55%)	9 / 139 (6.47%)	
occurrences (all)	6	11	
Influenza			
subjects affected / exposed	14 / 132 (10.61%)	13 / 139 (9.35%)	
occurrences (all)	17	15	
Gastroenteritis			
subjects affected / exposed	12 / 132 (9.09%)	17 / 139 (12.23%)	
occurrences (all)	15	24	
Pharyngitis			
subjects affected / exposed	8 / 132 (6.06%)	9 / 139 (6.47%)	
occurrences (all)	15	9	
Nasopharyngitis			
subjects affected / exposed	26 / 132 (19.70%)	26 / 139 (18.71%)	
occurrences (all)	50	48	
Rhinitis			
subjects affected / exposed	9 / 132 (6.82%)	13 / 139 (9.35%)	
occurrences (all)	9	24	
Respiratory tract infection			
subjects affected / exposed	0 / 132 (0.00%)	7 / 139 (5.04%)	
occurrences (all)	0	8	
Tonsillitis			
subjects affected / exposed	6 / 132 (4.55%)	10 / 139 (7.19%)	
occurrences (all)	7	10	
Upper respiratory tract infection			
subjects affected / exposed	10 / 132 (7.58%)	20 / 139 (14.39%)	
occurrences (all)	13	27	
Viral upper respiratory tract infection			
subjects affected / exposed	3 / 132 (2.27%)	13 / 139 (9.35%)	
occurrences (all)	4	13	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported