

### Raw Body Weight Data - First 10 Records

Obs	TRTGRP	AnimalID	Day0	Final
1	NC	NC1	267	269
2	NC	NC2	287	290
3	NC	NC3	312	315
4	NC	NC4	310	313
5	NC	NC5	282	285
6	NC	NC6	265	266
7	DC	DC1	322	278
8	DC	DC2	359	305
9	DC	DC3	327	268
10	DC	DC4	320	276

### SDTM.VS Dataset - First 20 Records

Obs	TRTGRP	STUDYID	DOMAIN	USUBJID	VSTPT	VSTEST	VISIT	VISITNUM	VSORRES
1	DC	PRECLINICAL01	VS	DC1	Day0	Body Weight	Day0	1	322
2	DC	PRECLINICAL01	VS	DC1	Final	Body Weight	Final	2	278
3	DC	PRECLINICAL01	VS	DC2	Day0	Body Weight	Day0	1	359
4	DC	PRECLINICAL01	VS	DC2	Final	Body Weight	Final	2	305
5	DC	PRECLINICAL01	VS	DC3	Day0	Body Weight	Day0	1	327
6	DC	PRECLINICAL01	VS	DC3	Final	Body Weight	Final	2	268
7	DC	PRECLINICAL01	VS	DC4	Day0	Body Weight	Day0	1	320
8	DC	PRECLINICAL01	VS	DC4	Final	Body Weight	Final	2	276
9	DC	PRECLINICAL01	VS	DC5	Day0	Body Weight	Day0	1	354
10	DC	PRECLINICAL01	VS	DC5	Final	Body Weight	Final	2	300
11	DC	PRECLINICAL01	VS	DC6	Day0	Body Weight	Day0	1	325
12	DC	PRECLINICAL01	VS	DC6	Final	Body Weight	Final	2	266
13	HECHD	PRECLINICAL01	VS	HHD1	Day0	Body Weight	Day0	1	321
14	HECHD	PRECLINICAL01	VS	HHD1	Final	Body Weight	Final	2	278
15	HECHD	PRECLINICAL01	VS	HHD2	Day0	Body Weight	Day0	1	299
16	HECHD	PRECLINICAL01	VS	HHD2	Final	Body Weight	Final	2	262
17	HECHD	PRECLINICAL01	VS	HHD3	Day0	Body Weight	Day0	1	339
18	HECHD	PRECLINICAL01	VS	HHD3	Final	Body Weight	Final	2	285
19	HECHD	PRECLINICAL01	VS	HHD4	Day0	Body Weight	Day0	1	335
20	HECHD	PRECLINICAL01	VS	HHD4	Final	Body Weight	Final	2	281

### ADaM.ADVS Dataset - First 20 Records

Obs	TRTGRP	STUDYID	USUBJID	AVISIT	PARAM	PARAMCD	ABLFL	BASE	AVISITN	AVAL	CHG	PCHG	baselineval
1	DC	PRECLINICAL01	DC1	Day0	Body Weight	BW	Y	322	1	322	0	0.0000	322
2	DC	PRECLINICAL01	DC1	Final	Body Weight	BW		322	2	278	-44	-13.6646	322
3	DC	PRECLINICAL01	DC2	Day0	Body Weight	BW	Y	359	1	359	0	0.0000	359
4	DC	PRECLINICAL01	DC2	Final	Body Weight	BW		359	2	305	-54	-15.0418	359
5	DC	PRECLINICAL01	DC3	Day0	Body Weight	BW	Y	327	1	327	0	0.0000	327
6	DC	PRECLINICAL01	DC3	Final	Body Weight	BW		327	2	268	-59	-18.0428	327
7	DC	PRECLINICAL01	DC4	Day0	Body Weight	BW	Y	320	1	320	0	0.0000	320
8	DC	PRECLINICAL01	DC4	Final	Body Weight	BW		320	2	276	-44	-13.7500	320
9	DC	PRECLINICAL01	DC5	Day0	Body Weight	BW	Y	354	1	354	0	0.0000	354

Obs	TRTGRP	STUDYID	USUBJID	AVISIT	PARAM	PARAMCD	ABLFL	BASE	AVISITN	AVAL	CHG	PCHG	baselineval
10	DC	PRECLINICAL01	DC5	Final	Body Weight	BW		354	2	300	-54	-15.2542	354
11	DC	PRECLINICAL01	DC6	Day0	Body Weight	BW	Y	325	1	325	0	0.0000	325
12	DC	PRECLINICAL01	DC6	Final	Body Weight	BW		325	2	266	-59	-18.1538	325
13	HECHD	PRECLINICAL01	HHD1	Day0	Body Weight	BW	Y	321	1	321	0	0.0000	321
14	HECHD	PRECLINICAL01	HHD1	Final	Body Weight	BW		321	2	278	-43	-13.3956	321
15	HECHD	PRECLINICAL01	HHD2	Day0	Body Weight	BW	Y	299	1	299	0	0.0000	299
16	HECHD	PRECLINICAL01	HHD2	Final	Body Weight	BW		299	2	262	-37	-12.3746	299
17	HECHD	PRECLINICAL01	HHD3	Day0	Body Weight	BW	Y	339	1	339	0	0.0000	339
18	HECHD	PRECLINICAL01	HHD3	Final	Body Weight	BW		339	2	285	-54	-15.9292	339
19	HECHD	PRECLINICAL01	HHD4	Day0	Body Weight	BW	Y	335	1	335	0	0.0000	335
20	HECHD	PRECLINICAL01	HHD4	Final	Body Weight	BW		335	2	281	-54	-16.1194	335

### ADaM.ADVS Dataset - First 20 Records

#### The MEANS Procedure

Analysis Variable : AVAL						
TRTGRP	AVISIT	AVISITN	N Obs	N	Mean	Std Dev
DC	Day0	1	6	6	334.5000	17.2829
	Final	2	6	6	282.1667	16.4732
HECHD	Day0	1	6	6	316.5000	18.5014
	Final	2	6	6	271.8333	11.1967
HECLD	Day0	1	6	6	290.1667	21.7570
	Final	2	6	6	256.6667	7.0899
NC	Day0	1	6	6	287.1667	20.3117
	Final	2	6	6	289.6667	20.9539
STD	Day0	1	6	6	296.6667	6.7429
	Final	2	6	6	258.3333	10.9301
STDHECHD	Day0	1	6	6	322.6667	14.6788
	Final	2	6	6	301.3333	17.3743
STDHECLD	Day0	1	6	6	298.3333	21.1345
	Final	2	6	6	267.8333	15.5360

### Mean Body Weight by Treatment Group and Visit

TRTGRP	AVISIT	AVISITN	MeanBW	SD	N
DC	Day0	1	334.500	17.283	6
DC	Final	2	282.167	16.473	6
HECHD	Day0	1	316.500	18.501	6
HECHD	Final	2	271.833	11.197	6
HECLD	Day0	1	290.167	21.757	6
HECLD	Final	2	256.667	7.090	6
NC	Day0	1	287.167	20.312	6
NC	Final	2	289.667	20.954	6
STD	Day0	1	296.667	6.743	6
STD	Final	2	258.333	10.930	6
STDHECHD	Day0	1	322.667	14.679	6
STDHECHD	Final	2	301.333	17.374	6
STDHECLD	Day0	1	298.333	21.134	6

TRTGRP	AVISIT	AVISITN	MeanBW	SD	N
STDHECLD	Final	2	267.833	15.536	6

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### Mean Body Weight by Treatment Group and Visit

The MEANS Procedure

Analysis Variable : CHG				
TRTGRP	N Obs	N	Mean	Std Dev
DC	6	6	-52.3333	6.8313
HECHD	6	6	-44.6667	7.7115
HECLD	6	6	-33.5000	14.9499
NC	6	6	2.5000	0.8367
STD	6	6	-38.3333	12.4043
STDHECHD	6	6	-21.3333	6.3456
STDHECLD	6	6	-30.5000	7.2595

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### Change from Baseline Final Day by Treatment Group

TRTGRP	MeanCHG	SDCHG	N
DC	-52.3333	6.8313	6
HECHD	-44.6667	7.7115	6
HECLD	-33.5000	14.9499	6
NC	2.5000	0.8367	6
STD	-38.3333	12.4043	6
STDHECHD	-21.3333	6.3456	6
STDHECLD	-30.5000	7.2595	6

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Table 1: Mean Body Weight by Treatment Group and Visit

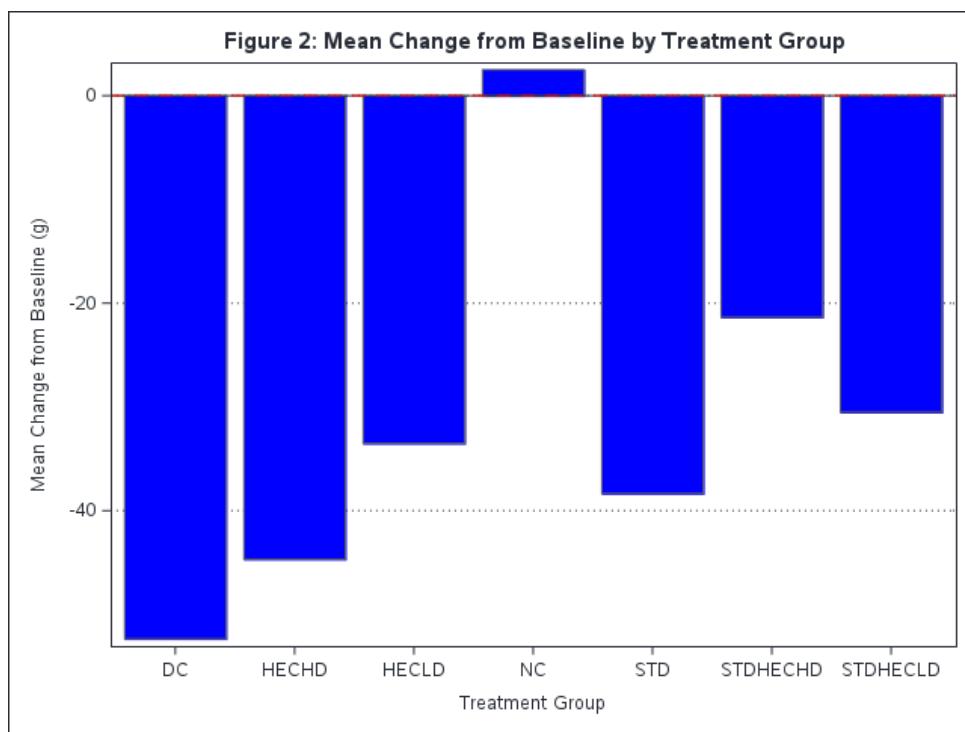
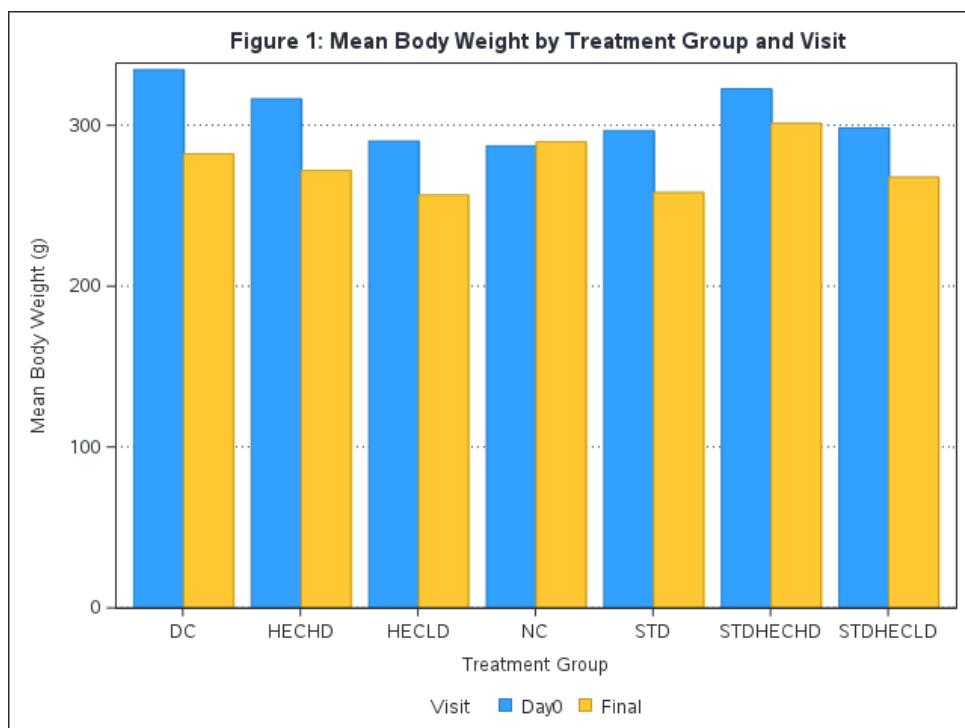
Treatment Group	Visit	Mean Body Weight (g)	Std Dev	N
DC	Day0	334.50	17.28	6
	Final	282.17	16.47	6
HECHD	Day0	316.50	18.50	6
	Final	271.83	11.20	6
HECLD	Day0	290.17	21.76	6
	Final	256.67	7.09	6
NC	Day0	287.17	20.31	6
	Final	289.67	20.95	6
STD	Day0	296.67	6.74	6
	Final	258.33	10.93	6
STDHECHD	Day0	322.67	14.68	6
	Final	301.33	17.37	6
STDHECLD	Day0	298.33	21.13	6
	Final	267.83	15.54	6

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Table 2: Change from Baseline (Final Visit)

Treatment Group	Mean Change (g)	Std Dev	N
DC	-52.3333	6.8313	6
HECHD	-44.6667	7.7115	6
HECLD	-33.5000	14.9499	6
NC	2.5000	0.8367	6
STD	-38.3333	12.4043	6
STDHECHD	-21.3333	6.3456	6

Treatment Group	Mean Change (g)	Std Dev	N
STDHECLD	-30.5000	7.2595	6



**ANCOVA: Change from Baseline by Treatment Group  
(Adjusted for Baseline Body Weight, NC as Reference)**

The GLM Procedure

Class Level Information		
Class	Levels	Values
TRTGRP	7	DC HECHD HECLD STD STDHECHD STDHECLD NC

Number of Observations Read 42

**ANCOVA: Change from Baseline by Treatment Group  
(Adjusted for Baseline Body Weight, NC as Reference)**

The GLM Procedure

Dependent Variable: CHG

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
<b>Model</b>	7	12398.24480	1771.17783	30.21	<.0001
<b>Error</b>	34	1993.58853	58.63496		
<b>Corrected Total</b>	41	14391.83333			

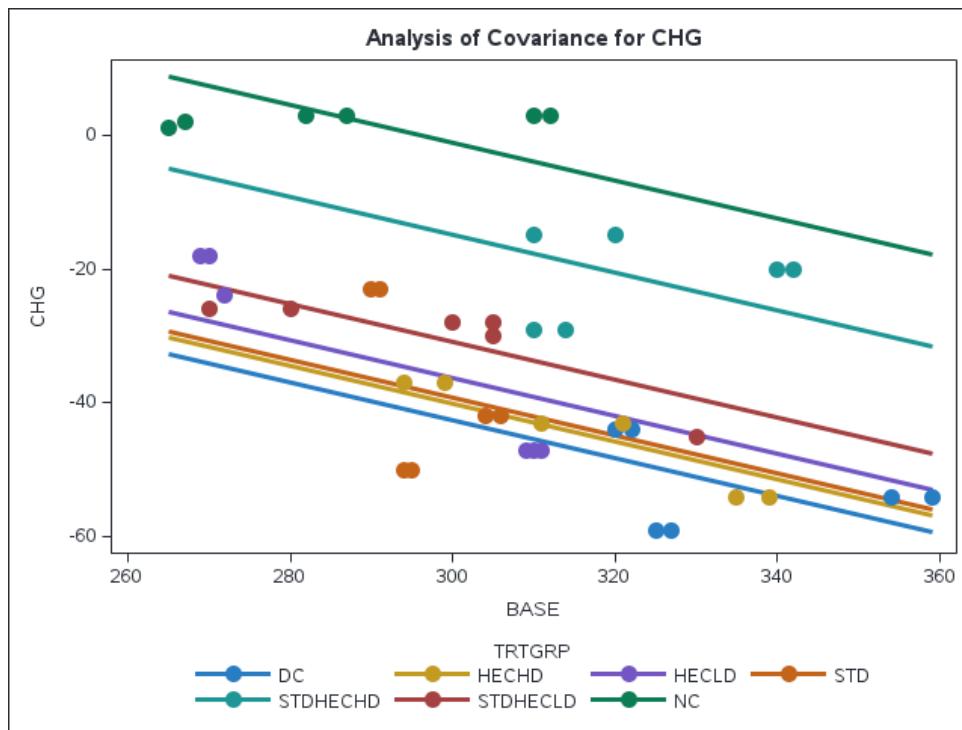
R-Square	Coeff Var	Root MSE	CHG Mean
0.861478	-24.56903	7.657347	-31.16667

Source	DF	Type I SS	Mean Square	F Value	Pr > F
<b>BASE</b>	1	4247.836380	4247.836380	72.45	<.0001
<b>TRTGRP</b>	6	8150.408424	1358.401404	23.17	<.0001

Source	DF	Type III SS	Mean Square	F Value	Pr > F
<b>BASE</b>	1	892.244804	892.244804	15.22	0.0004
<b>TRTGRP</b>	6	8150.408424	1358.401404	23.17	<.0001

Parameter	Estimate		Standard Error	t Value	Pr >  t	95% Confidence Limits	
<b>Intercept</b>	83.65169958	B	21.03694677	3.98	0.0003	40.89948002	126.40391915
<b>BASE</b>	-0.28259443		0.07244358	-3.90	0.0004	-0.42981749	-0.13537137
<b>TRTGRP DC</b>	-41.45719713	B	5.59490830	-7.41	<.0001	-52.82741880	-30.08697546
<b>TRTGRP HECHD</b>	-38.87723014	B	4.90516664	-7.93	<.0001	-48.84572812	-28.90873217
<b>TRTGRP HECLD</b>	-35.15221672	B	4.42630978	-7.94	<.0001	-44.14756046	-26.15687298
<b>TRTGRP STD</b>	-38.14868628	B	4.47421770	-8.53	<.0001	-47.24139064	-29.05598192
<b>TRTGRP STDHECHD</b>	-13.80123118	B	5.11457408	-2.70	0.0108	-24.19529628	-3.40716608
<b>TRTGRP STDHECLD</b>	-29.84436223	B	4.49437326	-6.64	<.0001	-38.97802761	-20.71069686
<b>TRTGRP NC</b>	0.00000000	B	.	.	.	.	.

**Note:** The X'X matrix has been found to be singular, and a generalized inverse was used to solve the normal equations. Terms whose estimates are followed by the letter 'B' are not uniquely estimable.



**ANCOVA: Change from Baseline by Treatment Group  
(Adjusted for Baseline Body Weight, NC as Reference)**

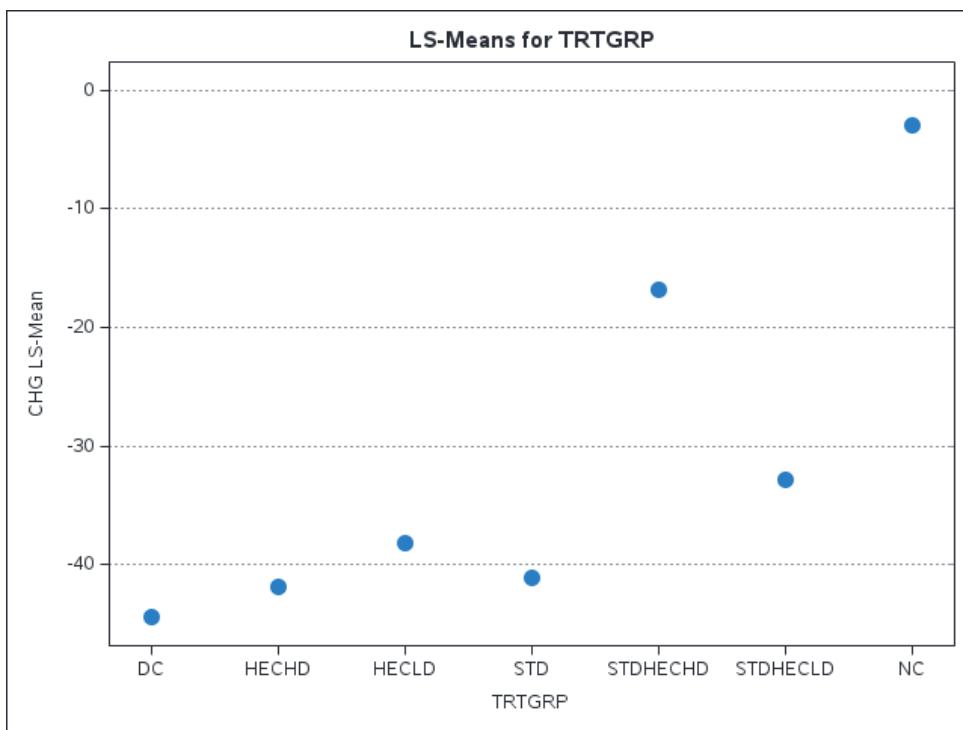
The GLM Procedure  
Least Squares Means  
Adjustment for Multiple Comparisons: Tukey-Kramer

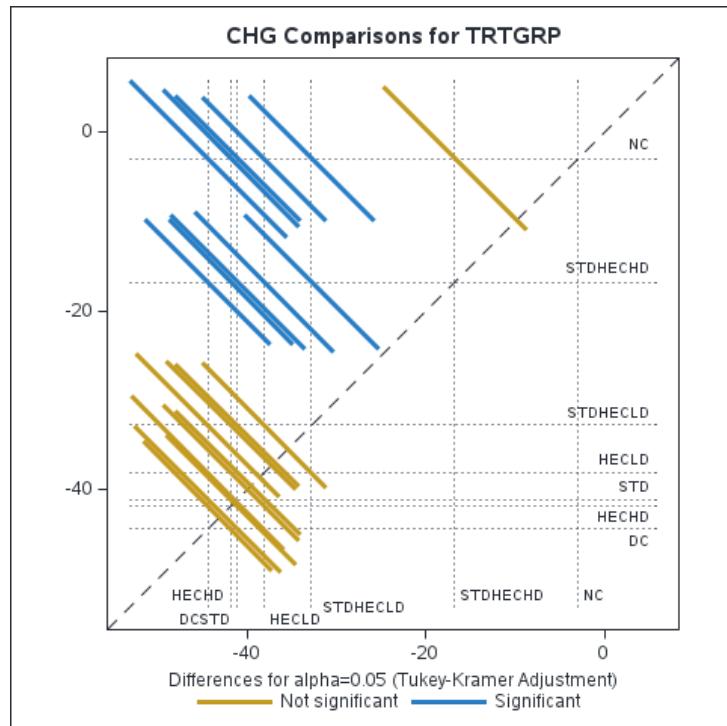
TRTGRP	CHG LSMEAN	LSMEAN Number
DC	-44.4408747	1
HECHD	-41.8609077	2
HECLD	-38.1358943	3
STD	-41.1323638	4
STDHECHD	-16.7849087	5
STDHECLD	-32.8280398	6
NC	-2.9836776	7

Least Squares Means for effect TRTGRP Pr >  t  for H0: LSMean(i)=LSMean(j)							
Dependent Variable: CHG							
i/j	1	2	3	4	5	6	7
1		0.9975	0.9062	0.9950	<.0001	0.2923	<.0001
2	0.9975		0.9860	1.0000	<.0001	0.4582	<.0001
3	0.9062	0.9860		0.9932	0.0026	0.8931	<.0001
4	0.9950	1.0000	0.9932		0.0003	0.5080	<.0001
5	<.0001	<.0001	0.0026	0.0003		0.0281	0.1296
6	0.2923	0.4582	0.8931	0.5080	0.0281		<.0001
7	<.0001	<.0001	<.0001	<.0001	0.1296	<.0001	

TRTGRP	CHG LSMEAN	95% Confidence Limits	
DC	-44.440875	-52.008364	-36.873386
HECHD	-41.860908	-48.379894	-35.341922
HECLD	-38.135894	-44.932479	-31.339310
STD	-41.132364	-47.650565	-34.614163
STDHECHD	-16.784909	-23.565434	-10.004383
STDHECLD	-32.828040	-39.295771	-26.360309
NC	-2.983678	-9.949454	3.982099

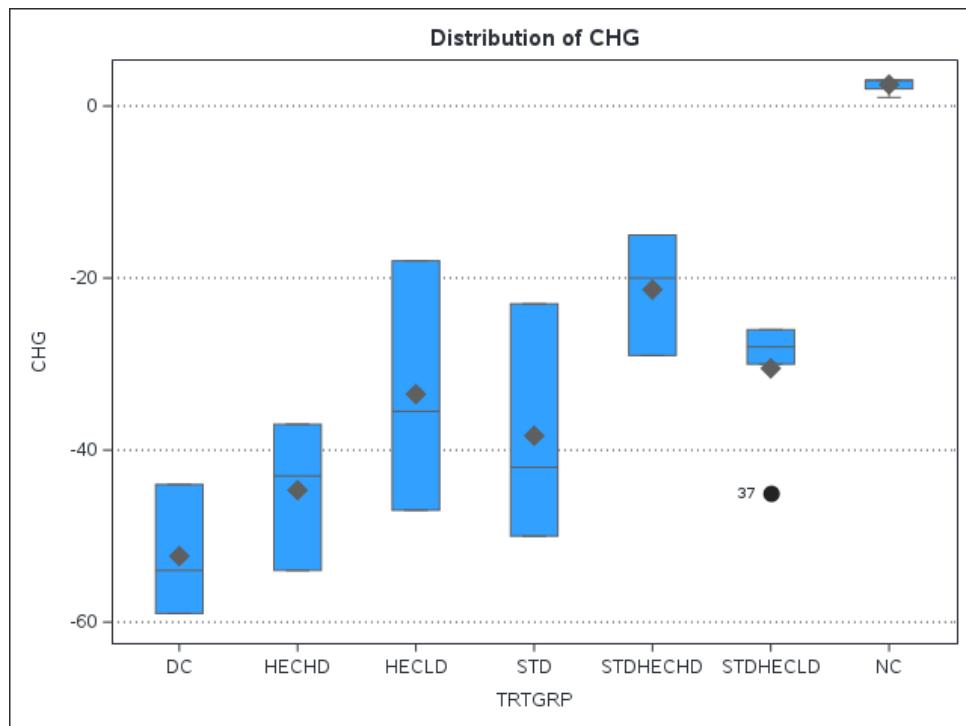
Least Squares Means for Effect TRTGRP				
i	j	Difference Between Means	Simultaneous 95% Confidence Limits for LSMean(i)-LSMean(j)	
1	2	-2.579967	-17.013119	11.853185
1	3	-6.304980	-23.415864	10.805903
1	4	-3.308511	-19.596517	12.979496
1	5	-27.655966	-41.757347	-13.554585
1	6	-11.612835	-27.704839	4.479169
1	7	-41.457197	-58.976714	-23.937681
2	3	-3.725013	-18.802380	11.352353
2	4	-0.728544	-15.284818	13.827730
2	5	-25.075999	-38.990026	-11.161972
2	6	-9.032868	-23.476762	5.411026
2	7	-38.877230	-54.236936	-23.517524
3	4	2.996470	-10.925363	16.918302
3	5	-21.350986	-37.035260	-5.666711
3	6	-5.307854	-19.274791	8.659082
3	7	-35.152217	-49.012463	-21.291970
4	5	-24.347455	-39.395024	-9.299887
4	6	-8.304324	-22.153015	5.544367
4	7	-38.148686	-52.158948	-24.138424
5	6	16.043131	1.139691	30.946571
5	7	-13.801231	-29.816662	2.214199
6	7	-29.844362	-43.917738	-15.770987





**ANCOVA: Change from Baseline by Treatment Group  
(Adjusted for Baseline Body Weight, NC as Reference)**

The GLM Procedure



**ANCOVA: Change from Baseline by Treatment Group  
(Adjusted for Baseline Body Weight, NC as Reference)**

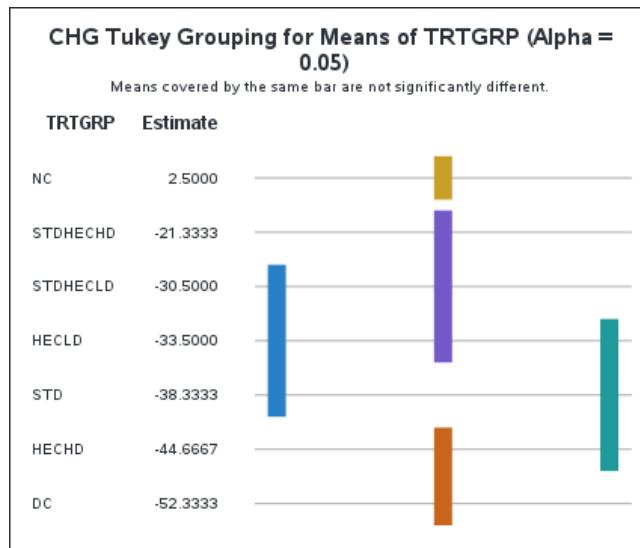
The GLM Procedure

Tukey's Studentized Range (HSD) Test for CHG

**Note:** This test controls the Type I experimentwise error rate, but it generally has a higher Type II error rate than REGWQ.

Alpha	0.05
Error Degrees of Freedom	34
Error Mean Square	58.63496

Critical Value of Studentized Range	4.42837
Minimum Significant Difference	13.844



**ANCOVA: Change from Baseline by Treatment Group  
(Adjusted for Baseline Body Weight, NC as Reference)**

The MEANS Procedure

Analysis Variable : CHG						
TRTGRP	N Obs	N	Mean	Std Dev	Minimum	Maximum
DC	6	6	-52.33333333	6.8313005	-59.0000000	-44.0000000
HECHD	6	6	-44.66666667	7.7114633	-54.0000000	-37.0000000
HECLD	6	6	-33.5000000	14.9499164	-47.0000000	-18.0000000
NC	6	6	2.5000000	0.8366600	1.0000000	3.0000000
STD	6	6	-38.33333333	12.4043003	-50.0000000	-23.0000000
STDHECHD	6	6	-21.33333333	6.3456022	-29.0000000	-15.0000000
STDHECLD	6	6	-30.5000000	7.2594766	-45.0000000	-26.0000000

**Data Interpretation: Body Weight Change by Group**

Group	Interpretation
DC Max	HECHD Second highest loss -44.67g - High dose effect
STD Thi	STDHECLD Moderate loss -30.50g - Combined low dose
HECLD Mod	STDHECHD Minimal loss -21.33g - Best combined treatment