9. Efficacy data

9.2 Secondary efficacy endpoint: QUICKI and Revised-QUICKI

- Change in QUICKI and Revised-QUICKI in telmisartan treated arm(s) after 24 weeks of treatment in comparison with control

The same ANCOVA model as the primary HOMAIR analysis is fitted to the two measures. The two alternative measures of insulin resistance are calculated as:

$$\text{QUICKI} = 1/(\log \text{G} + \log \text{I})$$

$$\text{Revised QUICKI} = 1/(\log \text{G} + \log \text{I} + \log \text{NEFA})$$

where G is fasting glucose (mg/dl), I is fasting insulin (μU/mL), and NEFA is plasma non esterified fatty acids concentration (mmol/l). Fasting glucose is recorded in mmol/l for the primary analysis, and the conversion factor for fasting glucose to convert from mmol/l to mg/dl is 18 (1 mmol/l = 18 mg/dl; http://www.diabetes.co.uk/blood-sugar-converter.html).

Table 9-1 Summary statistics for alternative measures QUICKI of insulin resistance at baseline and 24weeks by treatment group

	QUICKI at Baseline		QUICKI at 24weeks	
	Arm A Non intervention	Arm D Telmisartan (80mg daily)	Arm A Non intervention	Arm D Telmisartan (80mg daily)
N	100 (95.2%)	100 (94.3%)	89 (84.8%)	82 (77.4%)
Mean	0.117	0.118	0.115	0.116
Standard deviation	0.0092	0.0091	0.0093	0.0105
Min	0.097	0.093	0.092	0.083
Max	0.142	0.135	0.134	0.134
Median	0.117	0.119	0.115	0.116
Q1	0.111	0.113	0.11	0.109
Q3	0.124	0.123	0.122	0.124
Missing	5 (4.8%)	6 (5.7%)	16 (15.2%)	24 (22.6%)
N randomised	105	106	105	106

Table 9-2 Summary statistics for alternative measures Revised-QUICKI of insulin resistance at baseline and 24weeks by treatment group

	Revised-QUICKI at Baseline		Revised-QUICKI at 24weeks	
	Arm A Non intervention	Arm D Telmisartan (80mg daily)	Arm A Non intervention	Arm D Telmisartan (80mg daily)
N	100 (95.2%)	99 (93.4%)	88 (83.8%)	82 (77.4%)
Mean	0.132	0.133	0.132	0.133
Standard deviation	0.0168	0.0156	0.0176	0.0178
Min	0.101	0.096	0.099	0.097
Max	0.184	0.178	0.183	0.187

Median	0.130	0.132	0.129	0.130
Q1	0.122	0.123	0.119	0.121
Q3	0.142	0.143	0.14	0.143
Missing	5 (4.8%)	7 (6.6%)	17 (16.2%)	24 (22.6%)
N randomised	105	106	105	106

9.2.1 Checking for assumptions

Levene's test - check equal group variances

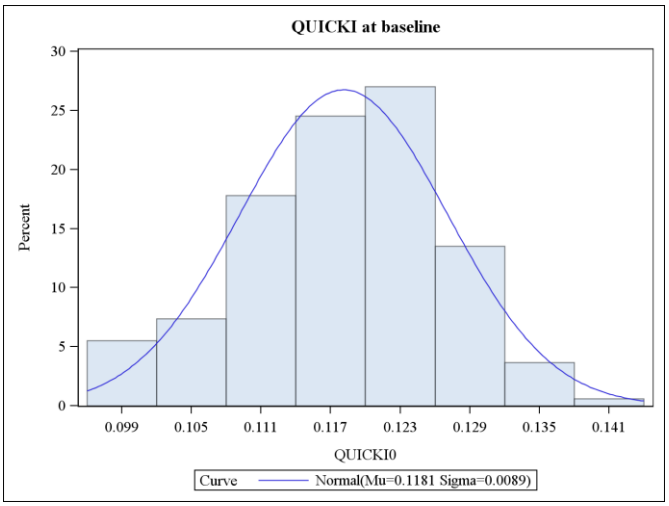
Table 9-3 Levene's Test for Homogeneity of QUICKI 24WK Variance

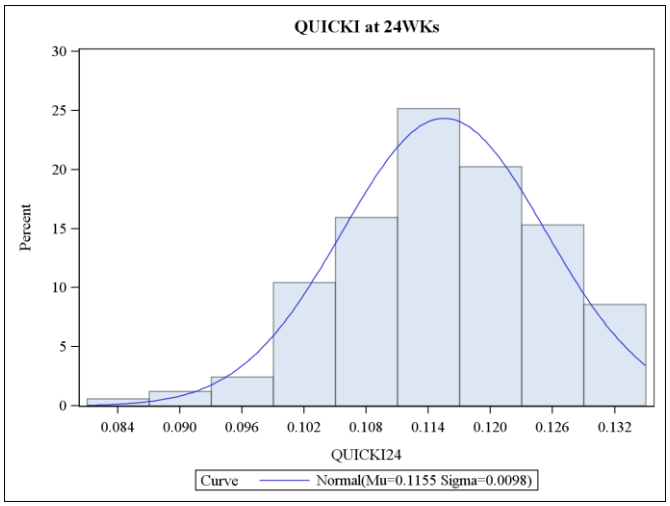
Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Treatment arm	1	1.268E-8	1.268E-8	0.68	0.4125

Table 9-4 Levene's Test for Homogeneity of Revised-QUICKI 24WK Variance

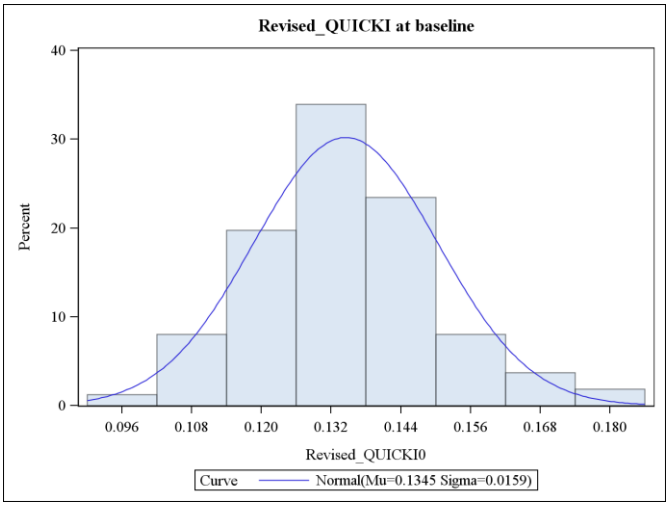
Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Treatment arm	1	2.06E-11	2.06E-11	0.00	0.9928

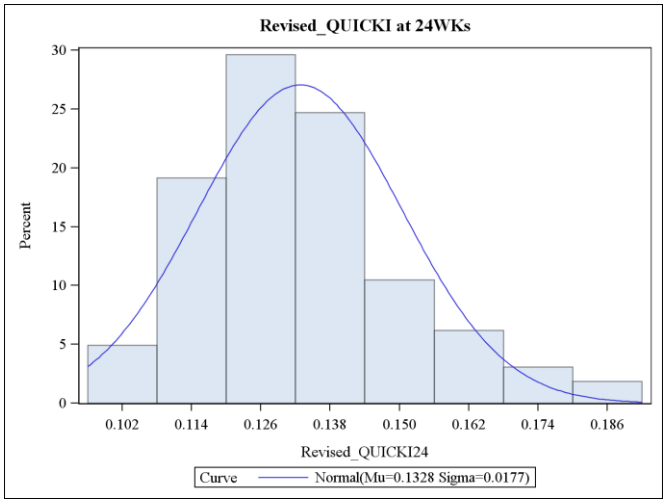
Histograms - check normality of QUICKI at baseline and 24 weeks





Histograms - check normality of Revised-QUICKI at baseline and 24 weeks





9.2.2 Estimates

Table 9-5 Model estimates for QUICKI

Variable	Parameter Estimate	Standard Error	t – value for treatment	Test Statistic
Intercept	0.04749	0.00901	-	
QUICKI at baseline	0.57321	0.07457	-	
Ethnicity (Non-Black)	0.00031	0.00165	-	
Arm D versus Arm A	0.00011	0.00133	0.0813	0.0813

The test statistic is 0.0813 and compared to the critical value of 2.086. As 0.0813 is not larger than the critical value we fail to reject the null hypothesis, i.e. no difference between Arm D and Arm A.

Table 9-6 Model estimates for Revised QUICKI

Variable	Parameter Estimate	Standard Error	t – value for treatment	Test Statistic
Intercept	0.06132	0.01089	-	
Revised QUICKI at baseline	0.50969	0.07869	-	
Ethnicity (Non-Black)	0.00299	0.00309	-	
Arm D versus Arm A	0.00110	0.00249	0.4418	0.4418

The test statistic is 0.4418 and compared to the critical value of 2.086. As 0.4418 is not larger than the critical value we fail to reject the null hypothesis, i.e. no difference between Arm D and Arm A.