

Secondary outcome 1: Percentage of participants in each group with 12-month HbA1c < 48 mmol/mol

Table 6.6-11: Percentage of participants in each group with 12-month HbA1c < 48 mmol/mol – Completeness of data (ITT)

Analysis status	Reason	CSII	MDI	Total
Included	Included	143 (99.3%)	142 (95.3%)	285 (97.3%)
Excluded	No local reason=(home visit); No central reason=(Quantity not sufficient)	0 (0%)	1 (0.7%)	1 (0.3%)
	No local reason=(home visit, see below); No central reason=(no sample received at labs)	0 (0%)	1 (0.7%)	1 (0.3%)
	WD from study prior to 12 months	1 (0.7%)	5 (3.4%)	6 (2%)

Note: This table is exactly the same for the HbA1c < 58.5 analysis.

Table 6.6-12: Percentage of participants in each group with 12-month HbA1c < 48 mmol/mol – Results (ITT)

	CSII	MDI	Overall	Difference in percentages (CSII-MDI) (95% CI)	Risk ratio (95% CI)	Chi-square p-value
HbA1c < 48 mmol/mol at 12 mths FU: n (%)	143	142	285	-5.0% (-14.0%, 3.9%)	0.75 (0.46,1.25)	0.28
No	121 (84.6%)	113 (79.6%)	234 (82.1%)			
Yes	22 (15.4%)	29 (20.4%)	51 (17.9%)			

Table 6.6-13: Percentage of participants in each group with 12-month HbA1c < 58.5 mmol/mol – Results (ITT)

	CSII	MDI	Overall	Difference in percentages (CSII-MDI) (95% CI)	Risk ratio (95% CI)	Chi-square p-value
HbA1c < 58.5 mmol/mol at 12 mths FU: n (%)	143	142	285	8.8% (-2.9%, 20.4%)	0.84 (0.67,1.06)	0.16
No	77 (53.8%)	64 (45.1%)	141 (49.5%)			
Yes	66 (46.2%)	78 (54.9%)	144 (50.5%)			