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Table 1: Distribution of patients according to group and out come

Outcome of the patients	Number of patients		Grand Total
	Nartana	Diclofenac	
Subject completed the study	29	26	55
Subject completed study, Non compliance reported	3	6	9
Lost to follow up (LTF)	6	6	12
Subject not dosed	2	2	4
Grand Total	40	40	80

Table 2: Distribution of patients in each group

Visit number/Weeks	Number of patients (N)		Grand Total
	Nartana	Diclofenac	
Visit V1	40	40	80
V2/Week 0	38	38	76
V4/ Week 4	34	33	67
V6/Week 8	31	30	61
V8/Week 12	31	32	63
ITT population (Patient taken at least one dose)	38	38	76
Per protocol population (Subject taken > 80 % of the drug)	29	26	55

Table 3: The Mean Change in Global WOMAC Score (Modified - CRD Pune Version) From Baseline to the End of 12 Weeks: ITT population.

Visit/ Week	NARTANA				DICLOFENAC				P value (Nartana Vs Diclofenac)
	N	WOMAC		P value (Pre Vs Post)	N	WOMAC		P value (Pre Vs Post)	
		Mean score (Mean± SD)	Mean change (Mean± SD)			Mean score (Mean± SD)	Mean change (Mean± SD)		
V2/ Week 0	38	34.03±7.61	-	-	38	34.03±10.44	-	-	1.0
V4/ Week 4	34	24.53±10.08	-9.59±9.71	0.001	33	24.91±8.55	-8.84±8.6	0.001	0.74
V6/ Week 8	31	18.97±9.89	-15.53±9.91	0.001	30	17.87±9.19	-14.53±9.90	0.001	0.69
V8/ Week 12	31	14.39±7.69	-19.67±8.15	0.001	32	14.59±8.29	-18.66±9.39	0.001	0.65

Paired t test is applied for within group comparison (pre Vs post).

Unpaired t test is applied for between group comparisons (Nartana Vs Diclofenac).

P value is significant if <0.05.

Figure 1: The Mean Change in Global WOMAC Score (Modified - CRD Pune Version) From Baseline to End of 12 Weeks: ITT population.

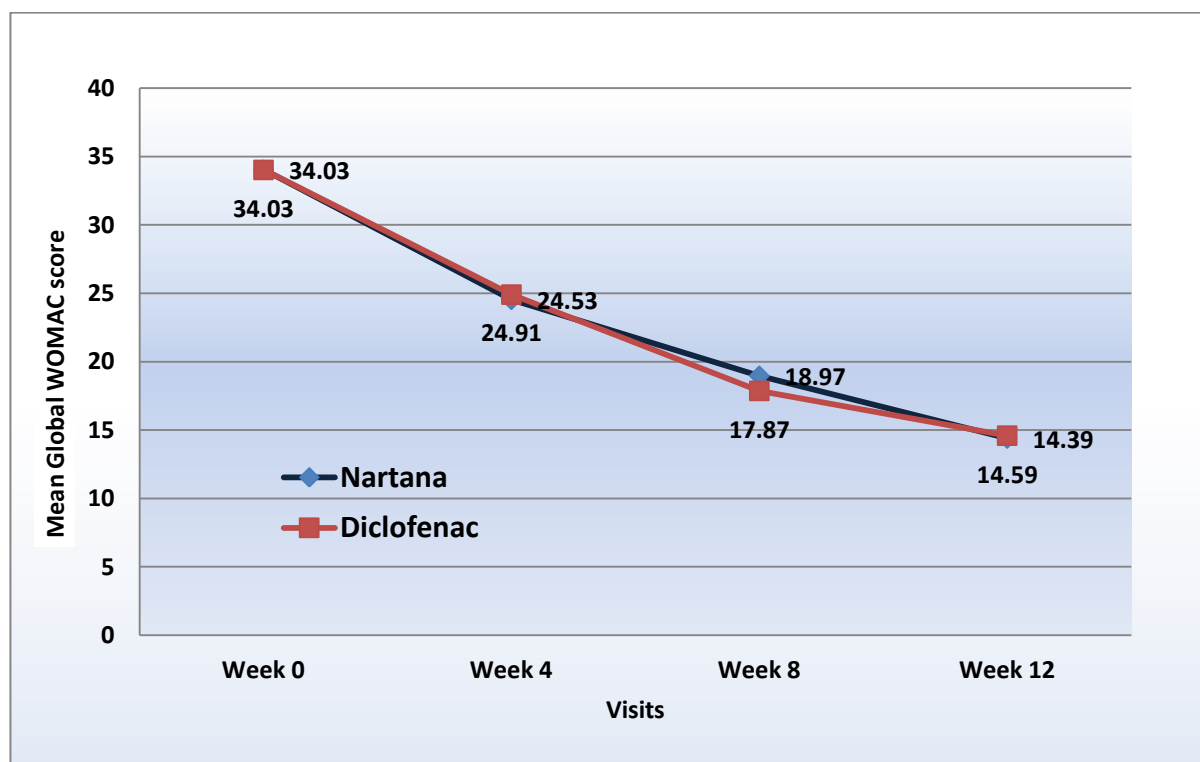


Table 4: The % Change in Global WOMAC Score (Modified - CRD Pune Version) From Baseline to End of Each Visit: ITT population.

Visit/ Week	NARTANA			DICLOFENAC			P value (Nartana Vs Diclofenac)
	N	WOMAC		N	WOMAC		
		Mean score (Mean± SD)	% change (Mean± SD)		Mean score (Mean± SD)	% change (Mean± SD)	
V2/ Week 0	38	34.03±7.61	-	38	34.03±10.44	-	1.0
V4/ Week 4	34	24.53±10.08	-27.07±25.90	33	24.91±8.55	-24.61±22.25	0.68
V6/ Week 8	31	18.97±9.89	-43.71±26.11	30	17.87±9.18	-43.50±26.38	0.97
V8/ Week 12	31	14.39±7.69	-57.49±19.25	32	14.59±8.29	-55.88 ±21.70	0.76

Unpaired t test is applied for between group comparison (Nartana Vs Diclofenac).
P value is significant if <0.05.

Figure 2: The % Change in Global WOMAC Score (Modified - CRD Pune Version) From Baseline to End of Each Visit: ITT population.

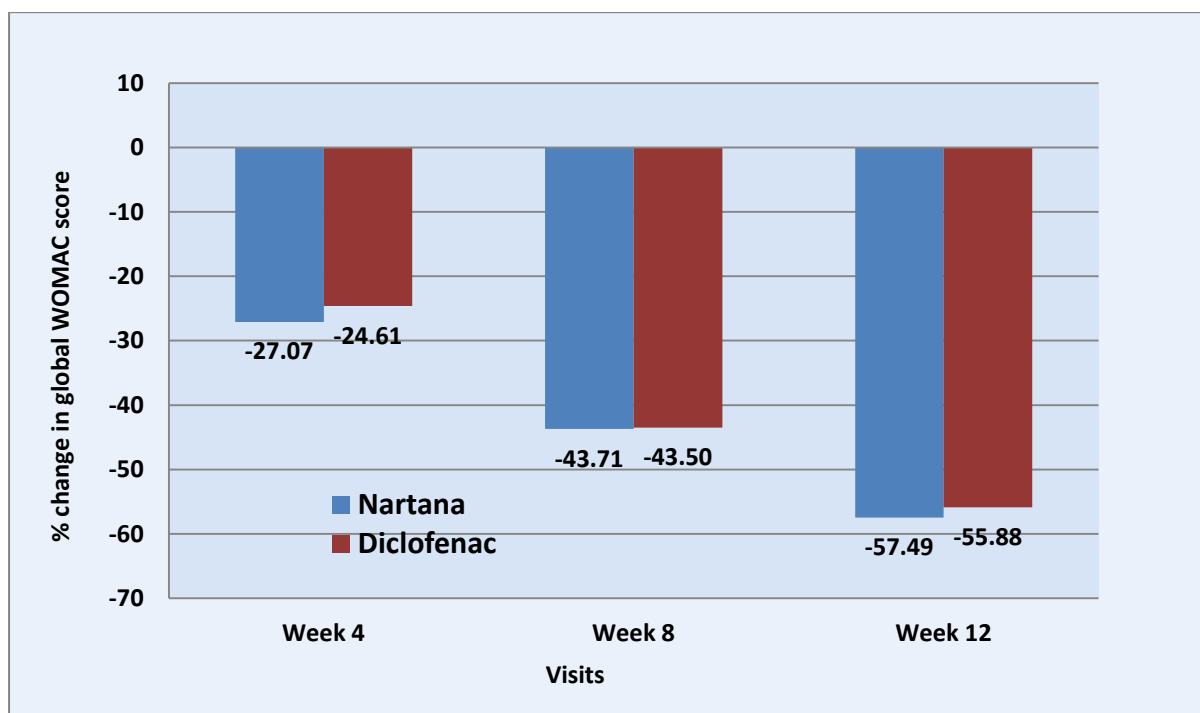


Table 5: The Mean Change in Global WOMAC Score (Modified - CRD Pune Version) From Baseline to the End of 12 Weeks: Per protocol population.

Visit/ weeks	NARTANA				DICLOFENAC				P value (Nartana Vs Diclofenac)
	N	WOMAC		P value (Pre Vs Post)	N	WOMAC		P value (Pre Vs Post)	
		Mean score (Mean± SD)	Mean change (Mean± SD)			Mean score (Mean± SD)	Mean change (Mean± SD)		
V2/ Week 0	29	34.00±7.97	-	-	26	34.12±8.52	-	-	0.96
V4/ Week 4	29	25.28±9.15	-8.72±8.69	0.001	26	27.00±6.56	-7.12±7.06	0.001	0.46
V6/ Week 8	29	19.52±9.63	-14.48±9.46	0.001	26	19.65±8.37	-14.46±9.65	0.001	0.99
V8/ Week 12	29	14.66±7.83	-19.34±8.10	0.001	26	14.19±7.19	-19.92±8.39	0.001	0.80

Paired t test is applied for within group comparison (pre Vs post).

Unpaired t test is applied for between group comparisons (Nartana Vs Diclofenac).

P value is significant if <0.05.

Figure 3: The Change in Global WOMAC Score (Modified - CRD Pune Version) From Baseline to the End of 12 Weeks: Per protocol population.

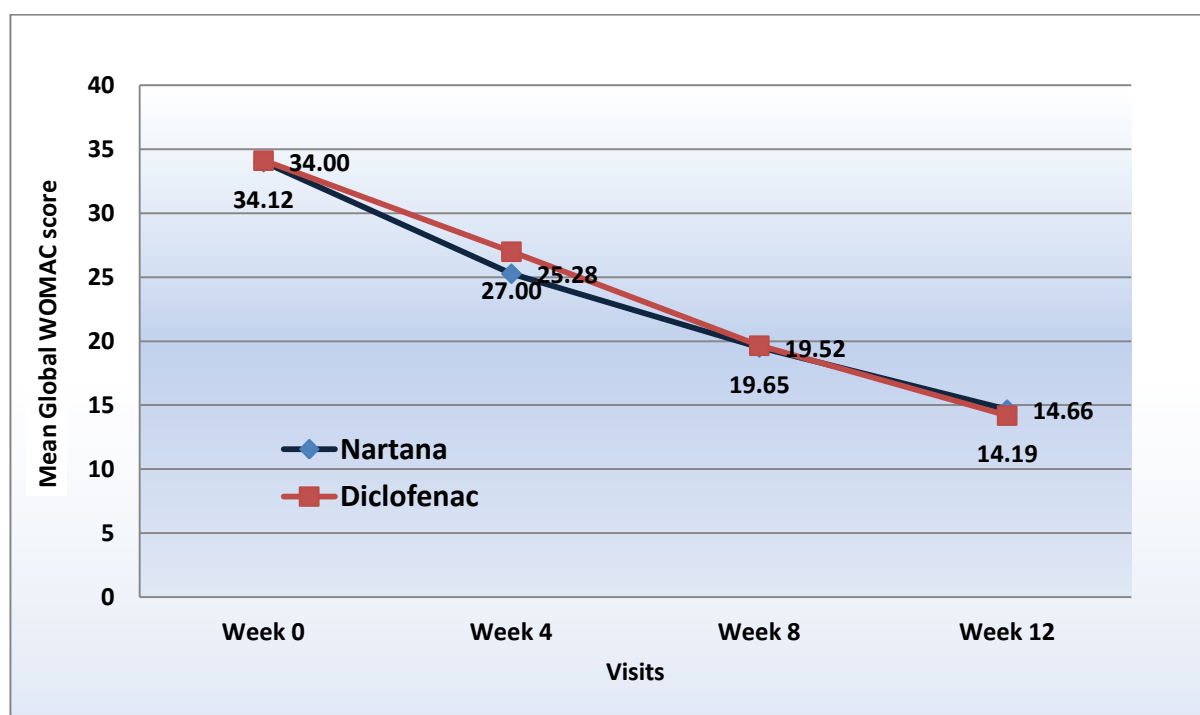


Table 6: The % Change in Global WOMAC Score (Modified - CRD Pune Version) From Baseline to End of Each Visit: Per Protocol population.

Visit	NARTANA			DICLOFENAC			P value (Nartana Vs Diclofenac)
	N	WOMAC		N	WOMAC		
		Mean score (Mean± SD)	% change (Mean± SD)		Mean score (Mean± SD)	% change (Mean± SD)	
V2/ Week 0	29	34.00±7.97	-	26	34.12±8.52	-	0.96
V4/ Week 4	29	25.28±9.15	-24.51±22.81	26	27.00±6.56	-19.03±17.37	0.33
V6/ Week 8	29	19.52±9.63	-41.94±24.99	26	19.65±8.37	-40.88±23.82	0.87
V8/ Week 12	29	14.66±7.83	-57.02±19.35	26	14.19±7.19	-58.31±18.94	0.80

Unpaired t test is applied for between group comparisons (Nartana Vs Diclofenac).
P value is significant if <0.05.

Figure 4: The % Change in Global WOMAC Score (Modified - CRD Pune Version) From Baseline to End of Each Visit: Per Protocol population.

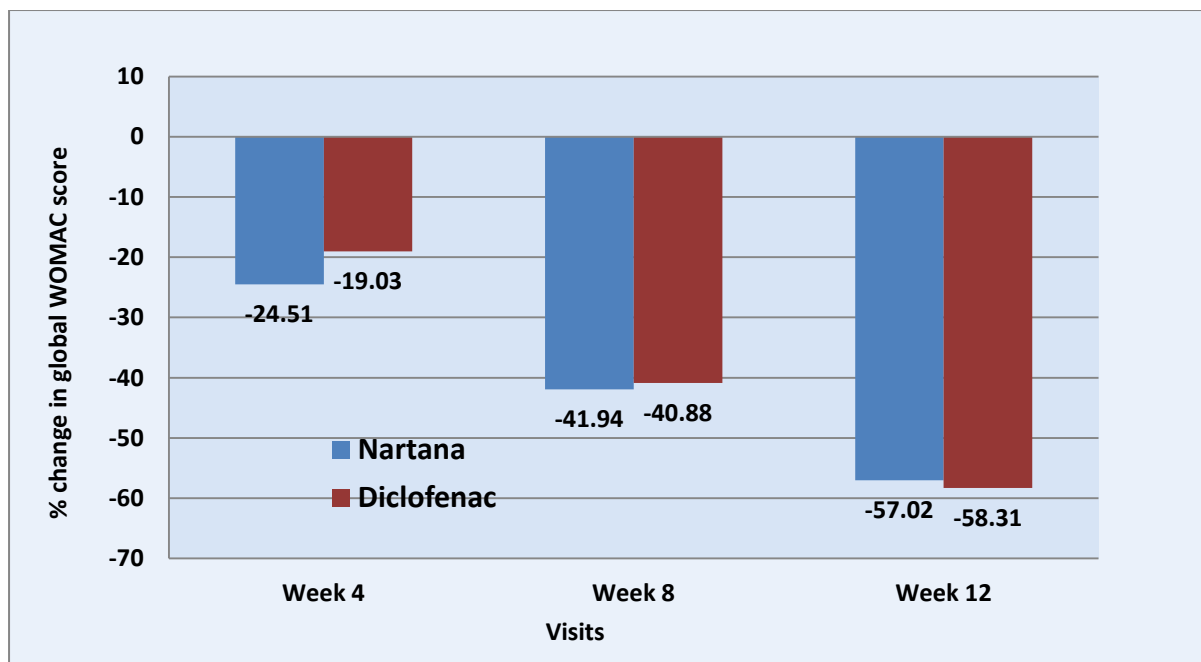


Table 7: The Mean Change in Health Assessment Questionnaire (HAQ) from baseline to the end of 12 weeks: ITT population.

Visit/ Weeks	NARTANA				DICLOFENAC				P value (Nartana Vs Diclofenac)
	N	HAQ		P value (Pre Vs Post)	N	HAQ		P value (Pre Vs Post)	
		Mean score (Mean± SD)	Mean change (Mean± SD)			Mean score (Mean± SD)	Mean change (Mean± SD)		
V2/ Week 0	38	37.08±11.64	-	-	38	36.00±13.56	-	-	0.88
V4/ Week 4	34	29.74±10.72	-7.62±8.26	0.001	33	28.85±10.72	-7.33±8.29	0.001	0.89
V6/ Week 8	31	23.71±10.12	-14.97±12.21	0.001	30	21.03±10.46	-15.17±12.19	0.001	0.95
V8/ Week 12	31	17.48±9.79	-21.84±12.33	0.001	32	16.28±8.44	-20.13±11.77	0.001	0.57

Paired t test is applied for within group comparison (pre Vs post).

Unpaired t test is applied for between group comparisons (Nartana Vs Diclofenac).

P value is significant if <0.05.

Figure 5: The Mean Change in Health Assessment Questionnaire (HAQ) from baseline to the end of 12 weeks: ITT population.

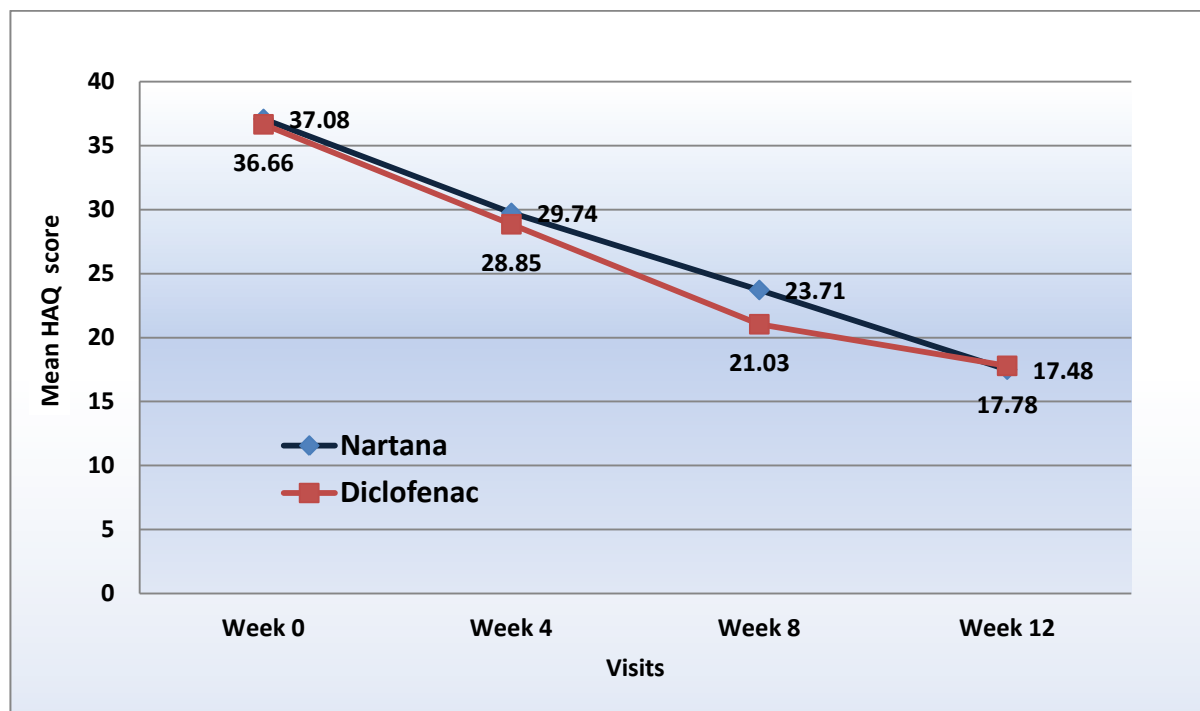


Table 8: The % change in HAQ from baseline to the end of 12 weeks: ITT population.

Visit Weeks	NARTANA			DICLOFENAC			P value (Nartana Vs Diclofenac)
	N	HAQ		N	HAQ		
		Mean score (Mean± SD)	% change (Mean± SD)		Mean score (Mean± SD)	% change (Mean± SD)	
V2/ Week 0	38	37.08±11.64	-	38	36.00±13.56	-	0.88
V4/ Week 4	34	29.74±10.72	-21.32±24.85	33	28.85±10.72	-20.75±20.11	0.92
V6/ Week 8	31	23.71±10.12	-37.73±26.29	30	21.03±10.46	-42.98±24.56	0.42
V8/ Week 12	31	17.48±9.79	-54.13 ± 23.44	32	16.28±8.44	-52.42±21.25	0.76

Unpaired t test is applied for between group comparisons (Nartana Vs Diclofenac).
P value is significant if <0.05.

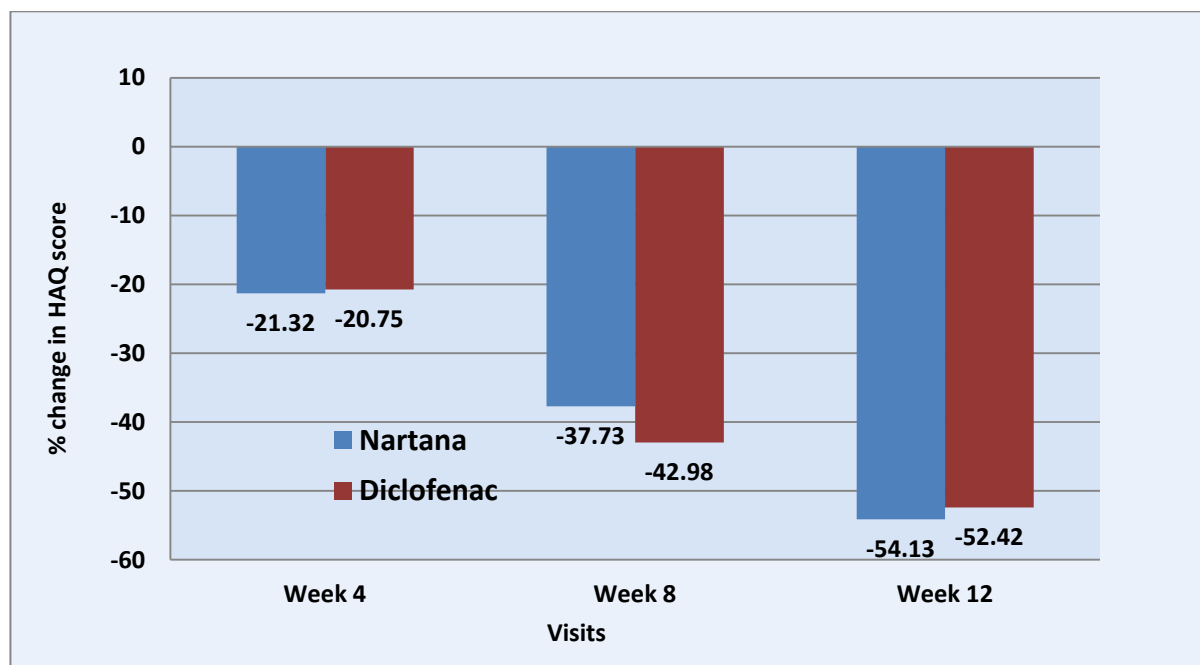
Figure 6: The % change in HAQ from baseline to the end of 12 weeks: ITT population.

Table 9: The Mean change in HAQ from baseline to the end of 12 weeks: Per Protocol population.

Visit/ Weeks	NARTANA				DICLOFENAC				P value (Nartana Vs Diclofenac)
	N	HAQ		P value (Pre Vs Post)	N	HAQ		P value (Pre Vs Post)	
		Mean score (Mean± SD)	Mean change (Mean± SD)			Mean score (Mean± SD)	Mean change (Mean± SD)		
V2/ Week 0	29	39.90±9.40	-	-	26	39.00±8.53	-	-	0.71
V4/ Week 4	29	31.86±8.32	-8.03±8.83	0.001	26	31.88±5.99	-7.12±8.53	0.001	0.70
V6/ Week 8	29	24.72±9.35	-15.17±12.54	0.001	26	23.73±8.23	-15.27±11.61	0.001	0.98
V8/ Week 12	29	17.90±9.89	-22.00±12.50	0.001	26	17.65±7.76	-21.35±10.03	0.001	0.83

Paired t test is applied for within group comparison (pre Vs post).

Unpaired t test is applied for between group comparisons (Nartana Vs Diclofenac).

P value is significant if <0.05.

Figure 7: The Mean change in HAQ from baseline to the end of 12 weeks: Per Protocol population.

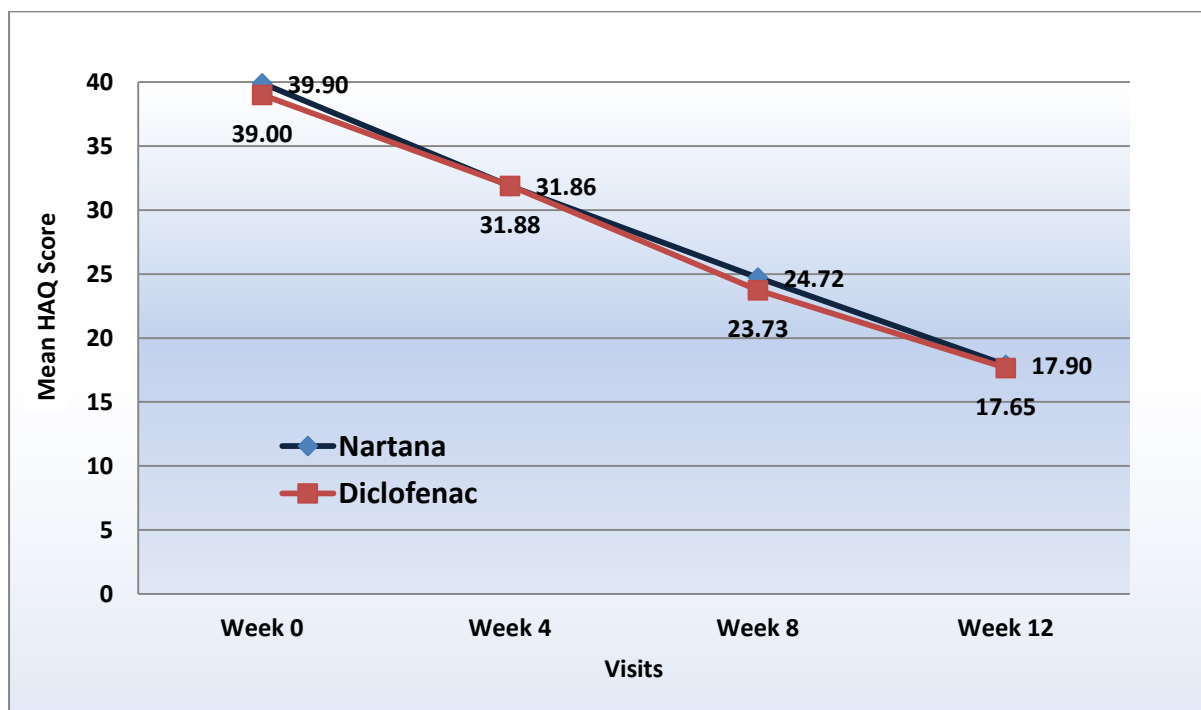


Table 10: The % change in HAQ from baseline to the end of 12 weeks: Per Protocol population.

Visit/ Weeks	NARTANA			DICLOFENAC			P value (Nartana Vs Diclofenac)
	N	HAQ		N	HAQ		
		Mean score (Mean± SD)	% change (Mean± SD)		Mean score (Mean± SD)	% change (Mean± SD)	
V2/ Week 0	29	39.90±9.40	-	26	39.00±8.53	-	0.71
V4/ Week 4	29	31.86±8.32	-18.08±21.61	26	31.88±5.99	-16.05±16.57	0.70
V6/ Week 8	29	24.72±9.35	-35.21±24.32	26	23.73±8.23	-37.20±20.38	0.74
V8/ Week 12	29	17.90±9.89	-53.73±23.42	26	17.65±7.76	-54.04±18.72	0.96

Unpaired t test is applied for between group comparisons (Nartana Vs Diclofenac).
P value is significant if <0.05.

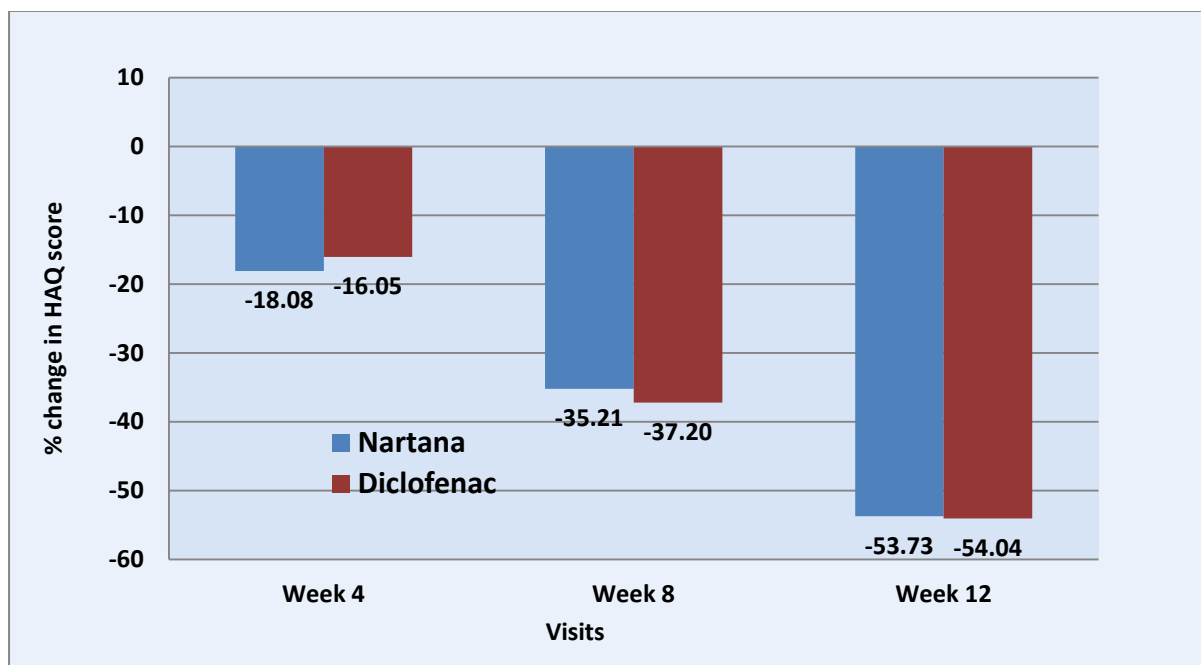
Figure 8: The % change in HAQ from baseline to the end of 12 weeks: Per Protocol population.

Table 11: Adverse events reported with Nartana (ALL Adverse events)

Subject Number	Group	Subject Initials	Adverse event	Severity	Date of onset	Date of resolution	Relationship	Outcome	Concomitant medication
34	Nartana	MSG	Heart burn	Moderate	21-05-2012	03-06-2012	Possible	Recovered	Yes
36	Nartana	SPJ	Hypertension	Severe	08-03-2012	28-03-2012	Unlikely	Recovering	Yes
50	Nartana	JYM	Nausea	Mild	15-02-2011	17-02-2011	Unlikely	Recovered	NO
50	Nartana		Vomiting	Moderate	16-02-2011	17-02-2011	Unlikely	Recovered	NO
55	Nartana	SSM	Headache	Moderate	26-01-2011	08-02-2011	Unlikely	Recovered	NO
66	Nartana	AME	Nausea	Moderate	10-03-2011	20-03-2011	Possible	Recovered	YES
66	Nartana		Headache	Severe	10-03-2011	20-03-2011	Possible	Recovered	YES
78	Nartana	SDP	Rash (red patches all over body with itching)	Moderate	07-08-2011	19-08-2011	Possible	Recovered	YES

Table 12: Adverse events reported with Diclofenac (ALL Adverse events)

Subject Number	Group	Subject Initials	Adverse event	Severity	Date of onset	Date of resolution	Relationship	Outcome	Concomitant medication
13	Diclofenac	MDG	Fungal Infection	Moderate	11-09-2011	20-01-2012	Unlikely	Recovering	Yes
46	Diclofenac	PAV	Nausea	Moderate	02-01-2011	03-01-2011	Possible	Recovered	No
46	Diclofenac		Abdominal pain	Mild	05-02-2011	06-02-2011	Possible	Recovered	No
54	Diclofenac	MMP	Nausea	Mild	29-01-2011	30-01-2011	Unlikely	Recovered	Yes
54	Diclofenac		Giddiness	Moderate	26-01-2011	30-01-2011	Unlikely	Recovered	NO
54	Diclofenac		Heart burn	Mild	30-01-2011	31-01-2011	Unlikely	Recovered	NO
54	Diclofenac		Heart burn	Mild	24-02-2011	06-03-2011	Unlikely	Recovered	Yes
54	Diclofenac		Nausea	Mild	26-03-2011	30-03-2011	Unlikely	Recovered	Yes

Table 13: Adverse events reported with Nartana (RELATED Adverse events)

Subject Number	Group	Subject Initials	Adverse event	Severity	Date of onset	Date of resolution	Relationship	Outcome	Concomitant medication
34	Nartana	MSG	Heart burn	Moderate	21-05-2012	03-06-2012	Possible	Recovered	Yes
66	Nartana	AME	Nausea	Moderate	10-03-2011	20-03-2011	Possible	Recovered	YES
66	Nartana		Headache	Severe	10-03-2011	20-03-2011	Possible	Recovered	YES
78	Nartana	SDP	Rash (red patches all over body with iteching)	Moderate	07-08-2011	19-08-2011	Possible	Recovered	YES

Table 14: Adverse events reported with Diclofenac (RELATED Adverse events)

Subject Number	Group	Subject Initials	Adverse event	Severity	Date of onset	Date of resolution	Relationship	Outcome	Concomitant medication
46	Diclofenac	PAV	Nausea	Moderate	02-01-2011	03-01-2011	Possible	Recovered	No
46	Diclofenac		Abdominal pain	Mild	05-02-2011	06-02-2011	Possible	Recovered	No