

- Secondary Endpoints -

This document contains the results for the secondary endpoints that it was not possible to include in the full data set, given their numbers and complexity.

The secondary endpoints of the study were:

1. Change in VAS score at baseline (Visit 0) and at the end of study (Visit 2) for the evaluation of LBP (investigator).
2. Change from baseline up to the end of the study in the hand-to-floor distance assessed at Visits 0, 1 and 2, measured by a cm graduated bar, for the evaluation of mobility restriction (investigator).
3. Change from baseline up to the end of the study in the degree of improvement in the functional disability, assessed at Visits 0, 1 and 2, measured by the Oswestry Disability Index (ODI).
4. Change in the patients' global impression at Visits 1 and 2, measured by the Patients' Global Impression of Change (PGIC) scale.
5. Change in the clinical global impression at Visits 1 and 2, measured by the Clinical Global Impression-Improvement (CGI-I) scale.

ODI, PGIC and CGI-I scale were evaluated at each time point using Cochran Mantel Haenszel test, in m-ITT and PP populations. VAS scale changes were evaluated by ANCOVA models.

1. Change in VAS score at baseline (Visit 0) and at the end of study (Visit 2)

	Ibuprofen 600mg	Paracetamol 500 mg/Ibuprofen 150 mg	p-value
m-ITT population			
LBP change			0.3132
N	87	83	.
Mean (SD)	-32.17 (23.73)	-32.67 (21.33)	.
Min - Max	-85 - 20	-69 - 20	.
PP population			
LBP change			0.2552
N	76	76	.
Mean (SD)	-32.92 (24.13)	-33.59 (21.46)	.
Min - Max	-85 - 10	-69 - 20	.

LBP change is the difference between LBP assessment at Visit 2 and Baseline.
m-ITT, modified intention-to-treat; PP, per protocol; SD, standard deviation

2. Change from baseline up to the end of the study in the hand-to-floor distance assessed at Visit 2, measured by a cm graduated bar.

	Ibuprofen 600 mg	Paracetamol 500 mg/Ibuprofen 150 mg	p-value
m-ITT population			
HTFD			0.7610
N	87	83	.
Mean (SD)	-4.43 (6.22)	-4.26 (6.84)	.
Min - Max	-29.5 - 8.5	-39.5 - 8.25	.
PP population			
HTFD			0.6903
N	76	76	.
Mean (SD)	-4.62 (5.91)	-4.69 (6.98)	.
Min - Max	-29.5 - 3	-39.5 - 8.25	.

HTFD (in cm) is calculated as the difference in mean2 and mean1, which are the means of the two HTDF measurements at Visit 2 and Screening/baseline, respectively.

3. Change from baseline up to the end of the study in the degree of improvement in the functional disability, assessed at Visits 1 and 2, measured by the Oswestry Disability Index (ODI)

ODI pain intensity

	Ibuprofen 600mg (N=88)	Paracetamol 500 mg/Ibuprofen 150 mg (N=83)	p-value
S1 - Pain Intensity at the screening			0.1739
1 - The pain is very mild at the moment	7 (8.0%)	8 (9.6%)	.
2 - The pain in moderate at the moment	44 (50.0%)	48 (57.8%)	.
3 - The pain is fairly severe at the moment	27 (30.7%)	21 (25.3%)	.
4 - The pain is very severe at the moment	9 (10.2%)	6 (7.2%)	.
5 - The pain is the worst imaginable at the moment	1 (1.1%)		.
S1 - Pain Intensity at Visit1			0.2308
0 - I have no pain at the moment	5 (5.7%)	12 (14.5%)	.
1 - The pain is very mild at the moment	47 (53.4%)	41 (49.4%)	.
2 - The pain in moderate at the moment	26 (29.5%)	19 (22.9%)	.
3 - The pain is fairly severe at the moment	3 (3.4%)	4 (4.8%)	.
S1 - Pain Intensity at Visit2 - ETV			0.4009
0 - I have no pain at the moment	17 (19.3%)	18 (21.7%)	.
1 - The pain is very mild at the moment	31 (35.2%)	37 (44.6%)	.
2 - The pain in moderate at the moment	32 (36.4%)	22 (26.5%)	.
3 - The pain is fairly severe at the moment	7 (8.0%)	4 (4.8%)	.
4 - The pain is very severe at the moment		2 (2.4%)	.

ODI pain intensity in PP

	Ibuprofen 600mg (N=76)	Paracetamol 500 mg/Ibuprofen 150 mg (N=76)	p-value
S1 - Pain Intensity at the screening			0.5281
1 - The pain is very mild at the moment	6 (7.9%)	5 (6.6%)	.
2 - The pain in moderate at the moment	41 (53.9%)	46 (60.5%)	.
3 - The pain is fairly severe at the moment	21 (27.6%)	19 (25.0%)	.
4 - The pain is very severe at the moment	7 (9.2%)	6 (7.9%)	.
5 - The pain is the worst imaginable at the moment	1 (1.3%)		.
S1 - Pain Intensity at Visit1			0.3137
0 - I have no pain at the moment	5 (6.6%)	11 (14.5%)	.
1 - The pain is very mild at the moment	43 (56.6%)	40 (52.6%)	.
2 - The pain in moderate at the moment	23 (30.3%)	18 (23.7%)	.
3 - The pain is fairly severe at the moment	3 (3.9%)	4 (5.3%)	.
S1 - Pain Intensity at Visit2 - ETV			0.2635
0 - I have no pain at the moment	13 (17.1%)	16 (21.1%)	.
1 - The pain is very mild at the moment	29 (38.2%)	35 (46.1%)	.
2 - The pain in moderate at the moment	28 (36.8%)	20 (26.3%)	.
3 - The pain is fairly severe at the moment	6 (7.9%)	4 (5.3%)	.
4 - The pain is very severe at the moment		1 (1.3%)	.

ODI self care

	Ibuprofen 600mg (N=88)	Paracetamol 500 mg/Ibuprofen 150 mg (N=83)	p-value
S2 - self care at the screening			0.9148
0 - I can look after myself normally without causing extra pain	27 (30.7%)	27 (32.5%)	.
1 - I can look after myself normally but it is very painful	26 (29.5%)	21 (25.3%)	.
2 - It is painful to look after myself and I am slow and careful	31 (35.2%)	32 (38.6%)	.
3 - I need some help but manage most of my personal care	3 (3.4%)	3 (3.6%)	.
4 - I need help every day in most aspects of self care	1 (1.1%)		.
S2 - self care at Visit1			0.8376
0 - I can look after myself normally without causing extra pain	45 (51.1%)	42 (50.6%)	.
1 - I can look after myself normally but it is very painful	29 (33.0%)	26 (31.3%)	.
2 - It is painful to look after myself and I am slow and careful	7 (8.0%)	8 (9.6%)	.
S2 - self care at Visit2 - ETV			0.4011
0 - I can look after myself normally without causing extra pain	62 (70.5%)	53 (63.9%)	.
1 - I can look after myself normally but it is very painful	18 (20.5%)	23 (27.7%)	.
2 - It is painful to look after myself and I am slow and careful	6 (6.8%)	6 (7.2%)	.
3 - I need some help but manage most of my personal care	1 (1.1%)		.
4 - I need help every day in most aspects of self care		1 (1.2%)	.

ODI self care in PP

	Ibuprofen 600mg (N=76)	Paracetamol 500 mg/Ibuprofen 150 mg (N=76)	p-value
S2 - self care at the screening			0.4813
0 - I can look after myself normally without causing extra pain	25 (32.9%)	22 (28.9%)	.
1 - I can look after myself normally but it is very painful	21 (27.6%)	19 (25.0%)	.
2 - It is painful to look after myself and I am slow and careful	28 (36.8%)	32 (42.1%)	.
3 - I need some help but manage most of my personal care	1 (1.3%)	3 (3.9%)	.
4 - I need help every day in most aspects of self care	1 (1.3%)		.
S2 - self care at Visit1			0.8479
0 - I can look after myself normally without causing extra pain	40 (52.6%)	39 (51.3%)	.
1 - I can look after myself normally but it is very painful	27 (35.5%)	26 (34.2%)	.
2 - It is painful to look after myself and I am slow and careful	7 (9.2%)	8 (10.5%)	.
S2 - self care at Visit2 - ETV			0.4011
0 - I can look after myself normally without causing extra pain	62 (70.5%)	53 (63.9%)	.
1 - I can look after myself normally but it is very painful	18 (20.5%)	23 (27.7%)	.
2 - It is painful to look after myself and I am slow and careful	6 (6.8%)	6 (7.2%)	.
3 - I need some help but manage most of my personal care	1 (1.1%)		.
4 - I need help every day in most aspects of self care		1 (1.2%)	.

ODI lifting

	Ibuprofen 600mg (N=88)	Paracetamol 500 mg/Ibuprofen 150 mg (N=83)	p-value
S3 - Lifting at the screening			0.9448
0 - I can lift heavy weights without extra pain	3 (3.4%)	3 (3.6%)	.
1 - I can lift heavy weights but it gives extra pain	41 (46.6%)	33 (39.8%)	.
2 - Pain prevents me from lifting heavy weights off the floor	21 (23.9%)	32 (38.6%)	.
3 - Pain prevents me from lifting heavy weights but I can manage	16 (18.2%)	8 (9.6%)	.
4 - I can lift only very light weights	6 (6.8%)	6 (7.2%)	.
5 - I cannot lift or carry anything at all	1 (1.1%)	1 (1.2%)	.
S3 - Lifting at Visit1			0.3278
0 - I can lift heavy weights without extra pain	15 (17.0%)	19 (22.9%)	.
1 - I can lift heavy weights but it gives extra pain	46 (52.3%)	41 (49.4%)	.
2 - Pain prevents me from lifting heavy weights off the floor	17 (19.3%)	13 (15.7%)	.
3 - Pain prevents me from lifting heavy weights but I can manage	1 (1.1%)	3 (3.6%)	.
4 - I can lift only very light weights	2 (2.3%)		.
S3 - Lifting at Visit2 - ETV			0.2305
0 - I can lift heavy weights without extra pain	28 (31.8%)	22 (26.5%)	.
1 - I can lift heavy weights but it gives extra pain	45 (51.1%)	43 (51.8%)	.
2 - Pain prevents me from lifting heavy weights off the floor	13 (14.8%)	16 (19.3%)	.
4 - I can lift only very light weights	1 (1.1%)	1 (1.2%)	.
5 - I cannot lift or carry anything at all		1 (1.2%)	.

ODI lifting in PP

	Ibuprofen 600mg (N=76)	Paracetamol 500 mg/Ibuprofen 150 p-value mg (N=76)	
S3 - Lifting at the screening			0.9364
0 - I can lift heavy weights without extra pain	3 (3.9%)	2 (2.6%)	.
1 - I can lift heavy weights but it gives extra pain	32 (42.1%)	28 (36.8%)	.
2 - Pain prevents me from lifting heavy weights off the floor	20 (26.3%)	32 (42.1%)	.
3 - Pain prevents me from lifting heavy weights but I can manage	15 (19.7%)	7 (9.2%)	.
4 - I can lift only very light weights	6 (7.9%)	6 (7.9%)	.
5 - I cannot lift or carry anything at all		1 (1.3%)	.
S3 - Lifting at Visit1			0.2178
0 - I can lift heavy weights without extra pain	12 (15.8%)	18 (23.7%)	.
1 - I can lift heavy weights but it gives extra pain	42 (55.3%)	39 (51.3%)	.
2 - Pain prevents me from lifting heavy weights off the floor	17 (22.4%)	13 (17.1%)	.
3 - Pain prevents me from lifting heavy weights but I can manage	1 (1.3%)	3 (3.9%)	.
4 - I can lift only very light weights	2 (2.6%)		.
S3 - Lifting at Visit2 - ETV			0.1621
0 - I can lift heavy weights without extra pain	24 (31.6%)	20 (26.3%)	.
1 - I can lift heavy weights but it gives extra pain	41 (53.9%)	39 (51.3%)	.
2 - Pain prevents me from lifting heavy weights off the floor	11 (14.5%)	16 (21.1%)	.
5 - I cannot lift or carry anything at all		1 (1.3%)	.

ODI Walking

	Ibuprofen 600mg (N=88)	Paracetamol 500 mg/Ibuprofen 150 p-value mg (N=83)	
S4 - Walking at the screening			0.0995
0 - Pain does not prevent me walking any distance	42 (47.7%)	30 (36.1%)	.
1 - Pain prevents me walking more than one mile	28 (31.8%)	32 (38.6%)	.
2 - Pain prevents me walking more than a quarter of a mile	16 (18.2%)	15 (18.1%)	.
3 - Pain prevents me walking more than 100 yards	1 (1.1%)	3 (3.6%)	.
4 - I can only walk using a stick or crutches	1 (1.1%)	3 (3.6%)	.
S4 - Walking at Visit1			0.4661
0 - Pain does not prevent me walking any distance	43 (48.9%)	38 (45.8%)	.
1 - Pain prevents me walking more than one mile	35 (39.8%)	34 (41.0%)	.
2 - Pain prevents me walking more than a quarter of a mile	3 (3.4%)	2 (2.4%)	.
3 - Pain prevents me walking more than 100 yards		2 (2.4%)	.
S4 - Walking at Visit2 - ETV			0.0915
0 - Pain does not prevent me walking any distance	60 (68.2%)	48 (57.8%)	.
1 - Pain prevents me walking more than one mile	25 (28.4%)	29 (34.9%)	.
2 - Pain prevents me walking more than a quarter of a mile	1 (1.1%)	5 (6.0%)	.
3 - Pain prevents me walking more than 100 yards	1 (1.1%)	1 (1.2%)	.

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ODI Walking in PP

	Ibuprofen 600mg (N=76)	Paracetamol 500 mg/Ibuprofen 150 mg (N=76)	p-value
S4 - Walking at the screening			0.1663
0 - Pain does not prevent me walking any distance	35 (46.1%)	26 (34.2%)	.
1 - Pain prevents me walking more than one mile	24 (31.6%)	30 (39.5%)	.
2 - Pain prevents me walking more than a quarter of a mile	15 (19.7%)	15 (19.7%)	.
3 - Pain prevents me walking more than 100 yards	1 (1.3%)	3 (3.9%)	.
4 - I can only walk using a stick or crutches	1 (1.3%)	2 (2.6%)	.
S4 - Walking at Visit1			0.5518
0 - Pain does not prevent me walking any distance	38 (50.0%)	36 (47.4%)	.
1 - Pain prevents me walking more than one mile	33 (43.4%)	33 (43.4%)	.
2 - Pain prevents me walking more than a quarter of a mile	3 (3.9%)	2 (2.6%)	.
3 - Pain prevents me walking more than 100 yards		2 (2.6%)	.
S4 - Walking at Visit2 - ETV			0.0316
0 - Pain does not prevent me walking any distance	53 (69.7%)	43 (56.6%)	.
1 - Pain prevents me walking more than one mile	22 (28.9%)	27 (35.5%)	.
2 - Pain prevents me walking more than a quarter of a mile	1 (1.3%)	5 (6.6%)	.
3 - Pain prevents me walking more than 100 yards		1 (1.3%)	.

ODI Sitting

	Ibuprofen 600mg (N=88)	Paracetamol 500 mg/Ibuprofen 150 mg (N=83)	p-value
S5 - Sitting at the screening			0.5092
0 - I can sit in any chair as long as I like	7 (8.0%)	3 (3.6%)	.
1 - I can sit in my favourite chair as long as I like	14 (15.9%)	16 (19.3%)	.
2 - Pain prevents me from sitting for more than 1 hour	50 (56.8%)	46 (55.4%)	.
3 - Pain prevents me from sitting for more than half an hour	13 (14.8%)	13 (15.7%)	.
4 - Pain prevents me from sitting for more than 10 minutes	3 (3.4%)	4 (4.8%)	.
5 - Pain prevents me from sitting at all	1 (1.1%)	1 (1.2%)	.
S5 - Sitting at Visit1			0.2918
0 - I can sit in any chair as long as I like	15 (17.0%)	19 (22.9%)	.
1 - I can sit in my favourite chair as long as I like	40 (45.5%)	36 (43.4%)	.
2 - Pain prevents me from sitting for more than 1 hour	22 (25.0%)	19 (22.9%)	.
3 - Pain prevents me from sitting for more than half an hour	4 (4.5%)	2 (2.4%)	.
S5 - Sitting at Visit2 - ETV			0.087
0 - I can sit in any chair as long as I like	28 (31.8%)	18 (21.7%)	.
1 - I can sit in my favourite chair as long as I like	37 (42.0%)	43 (51.8%)	.
2 - Pain prevents me from sitting for more than 1 hour	22 (25.0%)	16 (19.3%)	.
3 - Pain prevents me from sitting for more than half an hour		4 (4.8%)	.
4 - Pain prevents me from sitting for more than 10 minutes		1 (1.2%)	.
5 - Pain prevents me from sitting at all		1 (1.2%)	.

ODI Sitting in PP

	Ibuprofen 600mg (N=76)	Paracetamol 500 mg/Ibuprofen 150 mg (N=76)	p-value
S5 - Sitting at the screening			0.4704
0 - I can sit in any chair as long as I like	6 (7.9%)	2 (2.6%)	.
1 - I can sit in my favourite chair as long as I like	11 (14.5%)	14 (18.4%)	.
2 - Pain prevents me from sitting for more than 1 hour	45 (59.2%)	43 (56.6%)	.
3 - Pain prevents me from sitting for more than half an hour	10 (13.2%)	13 (17.1%)	.
4 - Pain prevents me from sitting for more than 10 minutes	3 (3.9%)	3 (3.9%)	.
5 - Pain prevents me from sitting at all	1 (1.3%)	1 (1.3%)	.
S5 - Sitting at Visit1			0.3035
0 - I can sit in any chair as long as I like	13 (17.1%)	18 (23.7%)	.
1 - I can sit in my favourite chair as long as I like	37 (48.7%)	34 (44.7%)	.
2 - Pain prevents me from sitting for more than 1 hour	20 (26.3%)	19 (25.0%)	.
3 - Pain prevents me from sitting for more than half an hour	4 (5.3%)	2 (2.6%)	.
S5 - Sitting at Visit2 - ETV			0.1871
0 - I can sit in any chair as long as I like	24 (31.6%)	18 (23.7%)	.
1 - I can sit in my favourite chair as long as I like	33 (43.4%)	39 (51.3%)	.
2 - Pain prevents me from sitting for more than 1 hour	19 (25.0%)	14 (18.4%)	.
3 - Pain prevents me from sitting for more than half an hour		3 (3.9%)	.
4 - Pain prevents me from sitting for more than 10 minutes		1 (1.3%)	.
5 - Pain prevents me from sitting at all		1 (1.3%)	.

ODI Standing

	(N=88)	Paracetamol 500 mg/Ibuprofen 150 mg (N=83)	p-value
S6 - Standing at the screening			0.8374
0 - I can stand as long as I want without extra pain	9 (10.2%)	5 (6.0%)	.
1 - I can stand as long as I want but it gives me extra pain	25 (28.4%)	27 (32.5%)	.
2 - Pain prevents me from standing for more than 1 hour	29 (33.0%)	33 (39.8%)	.
3 - Pain prevents me from standing for more than half an hour	19 (21.6%)	13 (15.7%)	.
4 - Pain prevents me from standing for more than 10 minutes	6 (6.8%)	5 (6.0%)	.
S6 - Standing at Visit1			0.7082
0 - I can stand as long as I want without extra pain	19 (21.6%)	21 (25.3%)	.
1 - I can stand as long as I want but it gives me extra pain	40 (45.5%)	35 (42.2%)	.
2 - Pain prevents me from standing for more than 1 hour	19 (21.6%)	17 (20.5%)	.
3 - Pain prevents me from standing for more than half an hour	3 (3.4%)	3 (3.6%)	.
S6 - Standing at Visit2 - ETV			0.8975
0 - I can stand as long as I want without extra pain	26 (29.5%)	28 (33.7%)	.
1 - I can stand as long as I want but it gives me extra pain	44 (50.0%)	41 (49.4%)	.
2 - Pain prevents me from standing for more than 1 hour	15 (17.0%)	9 (10.8%)	.
3 - Pain prevents me from standing for more than half an hour	2 (2.3%)	4 (4.8%)	.
4 - Pain prevents me from standing for more than 10 minutes		1 (1.2%)	.

ODI Standing in PP

	Ibuprofen 600mg (N=76)	Paracetamol 500 mg/Ibuprofen 150 mg (N=76)	p-value
S6 - Standing at the screening			1
0 - I can stand as long as I want without extra pain	8 (10.5%)	5 (6.6%)	.
1 - I can stand as long as I want but it gives me extra pain	21 (27.6%)	23 (30.3%)	.
2 - Pain prevents me from standing for more than 1 hour	26 (34.2%)	31 (40.8%)	.
3 - Pain prevents me from standing for more than half an hour	16 (21.1%)	12 (15.8%)	.
4 - Pain prevents me from standing for more than 10 minutes	5 (6.6%)	5 (6.6%)	.
S6 - Standing at Visit1			0.6856
0 - I can stand as long as I want without extra pain	16 (21.1%)	19 (25.0%)	.
1 - I can stand as long as I want but it gives me extra pain	37 (48.7%)	34 (44.7%)	.
2 - Pain prevents me from standing for more than 1 hour	18 (23.7%)	17 (22.4%)	.
3 - Pain prevents me from standing for more than half an hour	3 (3.9%)	3 (3.9%)	.
S6 - Standing at Visit2 - ETV			0.839
0 - I can stand as long as I want without extra pain	23 (30.3%)	27 (35.5%)	.
1 - I can stand as long as I want but it gives me extra pain	38 (50.0%)	36 (47.4%)	.
2 - Pain prevents me from standing for more than 1 hour	14 (18.4%)	9 (11.8%)	.
3 - Pain prevents me from standing for more than half an hour	1 (1.3%)	3 (3.9%)	.
4 - Pain prevents me from standing for more than 10 minutes		1 (1.3%)	.

ODI Sleeping

	Ibuprofen 600mg (N=88)	Paracetamol 500 mg/Ibuprofen 150 mg (N=83)	p-value
S7 - Sleeping at the screening			0.7455
0 - My sleep is never disturbed by pain	12 (13.6%)	15 (18.1%)	.
1 - My sleep is occasionally disturbed by pain	45 (51.1%)	35 (42.2%)	.
2 - Because of pain I have less than 6 hours sleep	16 (18.2%)	21 (25.3%)	.
3 - Because of pain I have less than 4 hours sleep	13 (14.8%)	12 (14.5%)	.
4 - Because of pain I have less than 2 hours sleep	2 (2.3%)		.
S7 - Sleeping at Visit1			0.5632
0 - My sleep is never disturbed by pain	29 (33.0%)	31 (37.3%)	.
1 - My sleep is occasionally disturbed by pain	42 (47.7%)	37 (44.6%)	.
2 - Because of pain I have less than 6 hours sleep	8 (9.1%)	6 (7.2%)	.
3 - Because of pain I have less than 4 hours sleep	2 (2.3%)	2 (2.4%)	.
S7 - Sleeping at Visit2 - ETV			0.3727
0 - My sleep is never disturbed by pain	40 (45.5%)	34 (41.0%)	.
1 - My sleep is occasionally disturbed by pain	42 (47.7%)	41 (49.4%)	.
2 - Because of pain I have less than 6 hours sleep	4 (4.5%)	7 (8.4%)	.
3 - Because of pain I have less than 4 hours sleep	1 (1.1%)	1 (1.2%)	.

ODI Sleeping in PP

	Ibuprofen 600mg (N=76)	Paracetamol 500 mg/Ibuprofen 150 mg (N=76)	p-value
S7 - Sleeping at the screening			0.8659
0 - My sleep is never disturbed by pain	11 (14.5%)	11 (14.5%)	.
1 - My sleep is occasionally disturbed by pain	36 (47.4%)	33 (43.4%)	.
2 - Because of pain I have less than 6 hours sleep	15 (19.7%)	21 (27.6%)	.
3 - Because of pain I have less than 4 hours sleep	12 (15.8%)	11 (14.5%)	.
4 - Because of pain I have less than 2 hours sleep	2 (2.6%)		.
S7 - Sleeping at Visit1			0.5526
0 - My sleep is never disturbed by pain	25 (32.9%)	28 (36.8%)	.
1 - My sleep is occasionally disturbed by pain	39 (51.3%)	37 (48.7%)	.
2 - Because of pain I have less than 6 hours sleep	8 (10.5%)	6 (7.9%)	.
3 - Because of pain I have less than 4 hours sleep	2 (2.6%)	2 (2.6%)	.
S7 - Sleeping at Visit2 - ETV			0.2617
0 - My sleep is never disturbed by pain	35 (46.1%)	29 (38.2%)	.
1 - My sleep is occasionally disturbed by pain	37 (48.7%)	40 (52.6%)	.
2 - Because of pain I have less than 6 hours sleep	3 (3.9%)	6 (7.9%)	.
3 - Because of pain I have less than 4 hours sleep	1 (1.3%)	1 (1.3%)	.

ODI Sex life

	Ibuprofen 600mg (N=88)	Paracetamol 500 mg/Ibuprofen 150 mg (N=83)	p-value
S8 - Sex life at the screening			0.8419
0 - My sex life is normal and causes no extra pain	35 (39.8%)	40 (48.2%)	.
1 - My sex life is normal but causes some extra pain	32 (36.4%)	26 (31.3%)	.
2 - My sex life is nearly normal but is very painful	6 (6.8%)	2 (2.4%)	.
3 - My sex life is severely restricted by pain	6 (6.8%)	7 (8.4%)	.
4 - My sex life is nearly absent because of pain	2 (2.3%)	2 (2.4%)	.
5 - Pain prevents any sex life at all	2 (2.3%)	3 (3.6%)	.
S8 - Sex life at Visit1			0.6853
0 - My sex life is normal and causes no extra pain	34 (38.6%)	37 (44.6%)	.
1 - My sex life is normal but causes some extra pain	19 (21.6%)	10 (12.0%)	.
2 - My sex life is nearly normal but is very painful	3 (3.4%)		.
3 - My sex life is severely restricted by pain	2 (2.3%)	4 (4.8%)	.
4 - My sex life is nearly absent because of pain	1 (1.1%)		.
5 - Pain prevents any sex life at all		1 (1.2%)	.
S8 - Sex life at Visit2 - ETV			0.8629
0 - My sex life is normal and causes no extra pain	37 (42.0%)	42 (50.6%)	.
1 - My sex life is normal but causes some extra pain	23 (26.1%)	10 (12.0%)	.
2 - My sex life is nearly normal but is very painful	3 (3.4%)	6 (7.2%)	.
3 - My sex life is severely restricted by pain		1 (1.2%)	.
4 - My sex life is nearly absent because of pain		1 (1.2%)	.

ODI Sex life in PP

	Ibuprofen 600mg (N=76)	Paracetamol 500 mg/Ibuprofen 150 p-value mg (N=76)	
S8 - Sex life at the screening			0.9962
0 - My sex life is normal and causes no extra pain	31 (40.8%)	35 (46.1%)	.
1 - My sex life is normal but causes some extra pain	28 (36.8%)	25 (32.9%)	.
2 - My sex life is nearly normal but is very painful	6 (7.9%)	2 (2.6%)	.
3 - My sex life is severely restricted by pain	3 (3.9%)	7 (9.2%)	.
4 - My sex life is nearly absent because of pain	2 (2.6%)	2 (2.6%)	.
5 - Pain prevents any sex life at all	2 (2.6%)	2 (2.6%)	.
S8 - Sex life at Visit1			0.6761
0 - My sex life is normal and causes no extra pain	32 (42.1%)	36 (47.4%)	.
1 - My sex life is normal but causes some extra pain	17 (22.4%)	9 (11.8%)	.
2 - My sex life is nearly normal but is very painful	3 (3.9%)		.
3 - My sex life is severely restricted by pain	2 (2.6%)	4 (5.3%)	.
4 - My sex life is nearly absent because of pain	1 (1.3%)		.
5 - Pain prevents any sex life at all		1 (1.3%)	.
S8 - Sex life at Visit2 - ETV			0.9388
0 - My sex life is normal and causes no extra pain	33 (43.4%)	38 (50.0%)	.
1 - My sex life is normal but causes some extra pain	19 (25.0%)	9 (11.8%)	.
2 - My sex life is nearly normal but is very painful	3 (3.9%)	6 (7.9%)	.
3 - My sex life is severely restricted by pain		1 (1.3%)	.

ODI Social life

	Ibuprofen 600mg (N=88)	Paracetamol 500 mg/Ibuprofen 150 p-value mg (N=83)	
S9 - Social life at the screening			0.7166
0 - My social life is normal and causes me no extra pain	29 (33.0%)	27 (32.5%)	.
1 - My social life is normal but increases the degree of pain	23 (26.1%)	17 (20.5%)	.
2 - Pain has no significant effect on my social life apart	21 (23.9%)	26 (31.3%)	.
3 - Pain has restricted my social life and I do not go out	13 (14.8%)	9 (10.8%)	.
4 - Pain has restricted social life to my home	1 (1.1%)	4 (4.8%)	.
5 - I have no social life because of pain	1 (1.1%)		.
S9 - Social life at Visit1			0.4037
0 - My social life is normal and causes me no extra pain	46 (52.3%)	47 (56.6%)	.
1 - My social life is normal but increases the degree of pain	23 (26.1%)	20 (24.1%)	.
2 - Pain has no significant effect on my social life apart	6 (6.8%)	6 (7.2%)	.
3 - Pain has restricted my social life and I do not go out	6 (6.8%)	3 (3.6%)	.
S9 - Social life at Visit2 - ETV			0.4757
0 - My social life is normal and causes me no extra pain	53 (60.2%)	57 (68.7%)	.
1 - My social life is normal but increases the degree of pain	26 (29.5%)	20 (24.1%)	.
2 - Pain has no significant effect on my social life apart	5 (5.7%)	2 (2.4%)	.
3 - Pain has restricted my social life and I do not go out	3 (3.4%)	4 (4.8%)	.

ODI Social life in PP

	Ibuprofen 600mg (N=76)	Paracetamol 500 mg/Ibuprofen 150 mg (N=76)	p-value
S9 - Social life at the screening			0.5787
0 - My social life is normal and causes me no extra pain	25 (32.9%)	22 (28.9%)	.
1 - My social life is normal but increases the degree of pain	21 (27.6%)	17 (22.4%)	.
2 - Pain has no significant effect on my social life apart	16 (21.1%)	25 (32.9%)	.
3 - Pain has restricted my social life and I do not go out	12 (15.8%)	9 (11.8%)	.
4 - Pain has restricted social life to my home	1 (1.3%)	3 (3.9%)	.
5 - I have no social life because of pain	1 (1.3%)	.	.
S9 - Social life at Visit1			0.4189
0 - My social life is normal and causes me no extra pain	41 (53.9%)	45 (59.2%)	.
1 - My social life is normal but increases the degree of pain	22 (28.9%)	19 (25.0%)	.
2 - Pain has no significant effect on my social life apart	6 (7.9%)	6 (7.9%)	.
3 - Pain has restricted my social life and I do not go out	5 (6.6%)	3 (3.9%)	.
S9 - Social life at Visit2 - ETV			0.5813
0 - My social life is normal and causes me no extra pain	48 (63.2%)	52 (68.4%)	.
1 - My social life is normal but increases the degree of pain	21 (27.6%)	19 (25.0%)	.
2 - Pain has no significant effect on my social life apart	5 (6.6%)	2 (2.6%)	.
3 - Pain has restricted my social life and I do not go out	2 (2.6%)	3 (3.9%)	.

ODI Travelling

	Ibuprofen 600mg (N=88)	Paracetamol 500 mg/Ibuprofen 150 mg (N=83)	p-value
S10 - Travelling at the screening			0.7531
0 - I can travel anywhere without pain	9 (10.2%)	7 (8.4%)	.
1 - I can travel anywhere but it gives extra pain	35 (39.8%)	37 (44.6%)	.
2 - Pain is bad but I manage journeys over two hours	30 (34.1%)	23 (27.7%)	.
3 - Pain restricts me to journeys of less than one hour	11 (12.5%)	12 (14.5%)	.
4 - Pain restricts me to short necessary journey under 30minutes	3 (3.4%)	3 (3.6%)	.
5 - Pain prevents me from travelling except to receive treatment		1 (1.2%)	.
S10 - Travelling at Visit1			0.4209
0 - I can travel anywhere without pain	23 (26.1%)	30 (36.1%)	.
1 - I can travel anywhere but it gives extra pain	47 (53.4%)	36 (43.4%)	.
2 - Pain is bad but I manage journeys over two hours	11 (12.5%)	8 (9.6%)	.
3 - Pain restricts me to journeys of less than one hour		2 (2.4%)	.
S10 - Travelling at Visit2 - ETV			0.7473
0 - I can travel anywhere without pain	34 (38.6%)	34 (41.0%)	.
1 - I can travel anywhere but it gives extra pain	45 (51.1%)	37 (44.6%)	.
2 - Pain is bad but I manage journeys over two hours	7 (8.0%)	11 (13.3%)	.
3 - Pain restricts me to journeys of less than one hour	1 (1.1%)	1 (1.2%)	.

ODI Travelling in PP

	Ibuprofen 600mg (N=76)	Paracetamol 500 mg/Ibuprofen 150 p-value mg (N=76)	
S10 - Travelling at the screening			0.6209
0 - I can travel anywhere without pain	8 (10.5%)	5 (6.6%)	.
1 - I can travel anywhere but it gives extra pain	28 (36.8%)	33 (43.4%)	.
2 - Pain is bad but I manage journeys over two hours	27 (35.5%)	23 (30.3%)	.
3 - Pain restricts me to journeys of less than one hour	11 (14.5%)	11 (14.5%)	.
4 - Pain restricts me to short necessary journey under 30minutes	2 (2.6%)	3 (3.9%)	.
5 - Pain prevents me from travelling except to receive treatment		1 (1.3%)	.
S10 - Travelling at Visit1			0.463
0 - I can travel anywhere without pain	21 (27.6%)	29 (38.2%)	.
1 - I can travel anywhere but it gives extra pain	43 (56.6%)	34 (44.7%)	.
2 - Pain is bad but I manage journeys over two hours	10 (13.2%)	8 (10.5%)	.
3 - Pain restricts me to journeys of less than one hour		2 (2.6%)	.
S10 - Travelling at Visit2 - ETV			0.9089
0 - I can travel anywhere without pain	29 (38.2%)	33 (43.4%)	.
1 - I can travel anywhere but it gives extra pain	39 (51.3%)	32 (42.1%)	.
2 - Pain is bad but I manage journeys over two hours	7 (9.2%)	10 (13.2%)	.
3 - Pain restricts me to journeys of less than one hour	1 (1.3%)	1 (1.3%)	.

4. Change in the patients' global impression at Visits 1 and 2, measured by the Patients' Global Impression of Change (PGIC) scale

	Ibuprofen 600 mg	Paracetamol 500 mg/ibuprofen 150 mg	p-value
m-ITT population	n=88	n=83	
PGIC at Visit 1			0.0539
1 Very much improved	10 (11.4%)	13 (15.7%)	.
2 Much improved	29 (33.0%)	40 (48.2%)	.
3 Minimally improved	40 (45.5%)	19 (22.9%)	.
4 No change	2 (2.3%)	4 (4.8%)	.
PGIC at Visit 2			0.6273
1 Very much improved	23 (26.1%)	17 (20.5%)	.
2 Much improved	18 (20.5%)	27 (32.5%)	.
3 Minimally improved	29 (33.0%)	27 (32.5%)	.
4 No change	14 (15.9%)	10 (12.0%)	.
5 Minimally worse	1 (1.1%)	2 (2.4%)	.
6 Much worse	2 (2.3%)		.
PP population	n=76	n=76	
PGIC at Visit1			0.0341
1 Very much improved	10 (13.2%)	13 (17.1%)	.
2 Much improved	25 (32.9%)	39 (51.3%)	.
3 Minimally improved	37 (48.7%)	18 (23.7%)	.
4 No change	2 (2.6%)	3 (3.9%)	.
PGIC at Visit2			0.6633
1 Very much improved	23 (30.3%)	17 (22.4%)	.
2 Much improved	14 (18.4%)	26 (34.2%)	.
3 Minimally improved	24 (31.6%)	23 (30.3%)	.
4 No change	13 (17.1%)	8 (10.5%)	.
5 Minimally worse	1 (1.3%)	2 (2.6%)	.
6 Much worse	1 (1.3%)		.

m-ITT, modified intention-to-treat; PGIC, Patients' Global Impression of Change; PP, per protocol

5. Change in the clinical global impression at Visits 1 and 2, measured by the Clinical Global Impression-Improvement (CGI-I) scale

	Ibuprofen 600mg	Paracetamol 500 mg/ibuprofen 150 mg	p-value
m-ITT population	n=88	n=83	
CGI-I at Visit 1			0.0137
1 - Very much improved	7 (8.0%)	16 (19.3%)	.
2 - Much improved	33 (37.5%)	37 (44.6%)	.
3 - Minimally improved	41 (46.6%)	20 (24.1%)	.
4 - No change		3 (3.6%)	.
CGI-I at Visit 2	22 (25.0%)		0.4597
1 - Very much improved		20 (24.1%)	.
2 - Much improved	21 (23.9%)	28 (33.7%)	.
3 - Minimally improved	29 (33.0%)	24 (28.9%)	.
4 - No change	12 (13.6%)	9 (10.8%)	.
5 - Minimally worse	3 (3.4%)	2 (2.4%)	.
PP population	n=76	n=76	
CGI-I at Visit1			0.0097
1 - Very much improved	7 (9.2%)	15 (19.7%)	.
2 - Much improved	29 (38.2%)	37 (48.7%)	.
3 - Minimally improved	38 (50.0%)	19 (25.0%)	.
4 - No change		2 (2.6%)	.
CGI-I at Visit2	22 (28.9%)		0.4904
1 - Very much improved		19 (25.0%)	.
2 - Much improved	17 (22.4%)	28 (36.8%)	.
3 - Minimally improved	25 (32.9%)	20 (26.3%)	.
4 - No change	10 (13.2%)	8 (10.5%)	.
5 - Minimally worse	2 (2.6%)	1 (1.3%)	.

CGI-I, Clinical Global Impression-Improvement; m-ITT, modified intention-to-treat; PP, per protocol