

FLOW CHART

		<i>TREATMENT PERIOD</i>				<i>FOLLOW-UP optional</i>
		Visit 1 Day 0	Visit 2 Day 7±1	Visit 3 Day 14±1	Visit 4 Day 21±1	(Visit 5) (Day 35±2)
Group 1 Medication:	Capsicum					
Group 2 Medication:	Placebo					
History / physical examination	x	(x)	(x)	x	x	
Diagnosis	x					
Sociodemographic data	x					
Check of inclusion and exclusion criteria	x					
Concomitant diseases and medications	x	x	x	x	x	
Patient information	x					
Informed consent obtained	x					
Patient number assigned	x					
Vital parameters	x	x	x	x	x	
Duration of sick leave	x	x	x	x	x	
Skin status	x	x	x	x	x	
Pain scores	x	x	x	x	x	
Adverse events	(x)	x	x	x	x	
Reasons for any study withdrawal		x	x	x	x	
Test medication and pain diary issued	x	x	x			
Appointment for the next visit	x	x	x	x		
Unused medication and pain diary collected		x	x	x		
Questionnaire on cream use		x	x	x		
Assessment of compliance		x	x	x		
Efficacy evaluation		x	x	x	x	
Safety evaluation		x	x	x	x	

Collectives analysed

		Capsicum		Placebo		Total	
Collective		N	%	N	%	N	%
Chronic soft tissue pain	Total Collective	64	100,0%	67	100,0%	131	100,0%
	Full Analysis Set (ITT)	64	100,0%	66	98,5%	130	99,2%
	Per-Protocol-Collective (PP)	58	90,6%	62	92,5%	120	91,6%
Chronic back pain with a vertebral component	Total Collective	71	100,0%	71	100,0%	142	100,0%
	Full Analysis Set (ITT)	71	100,0%	71	100,0%	142	100,0%
	Per-Protocol-Collective (PP)	58	81,7%	67	94,4%	125	88,0%
Total (including patients not allocated to one of the above groups)	Total Collective	140	100,0%	142	100,0%	282	100,0%
	Safety Collective	140	100,0%	141	99,3%	281	99,6%

Early discontinuation (ITT; percent numbers of the various reasons relate to the total of withdrawals within the concerned medication group)

		Capsicum		Placebo		Gesamt		
Study completed / or reason for withdrawal		N	%	N	%	N	%	
Chronic soft tissue pain	Yes	58	100,0%	65	100,0%	123	100,0%	
	No	Symptomfree early	3	50,0%	1	100,0%	4	57,1%
		Insufficient effect / deterioration of condition	2	33,3%			2	28,6%
		Patient refuses to continue, possibly because of strong local skin reaction	1	16,7%			1	14,3%
Chronic back pain with vertebral component	Yes	66	100,0%	68	100,0%	134	100,0%	
	No	Symptomfree early	1	20,0%	2	66,7%	3	37,5%
		Insufficient effect / deterioration of condition	1	20,0%	1	33,3%	2	25,0%
		Patient refuses to continue, possibly because of insufficient efficacy	1	20,0%			1	12,5%
		Strong local skin reaction	2	40,0%			2	25,0%

Protocol violations (ITT; more than one mention possible per patient)

		Capsicum		Placebo		Total	
Nature of protocol violation		N	%	N	%	N	%
cSTP	Inclusion criterion age violated	2	3,1%	2	3,0%	4	3,1%

		Capsicum		Placebo		Total	
Nature of protocol violation		N	%	N	%	N	%
	Non-permitted concomitant illness, relevant to efficacy	2	3,1%	1	1,5%	3	2,3%
	Non-permitted concomitant therapy or pretreatment not discontinued on time, relevant to efficacy	2	3,1%	2	3,0%	4	3,1%
	Serious postponement of study visit			1	1,5%	1	,8%
	Insufficient compliance	8	12,5%	5	7,5%	13	9,9%
	Early withdrawal from the study, (probably) for reasons of efficacy	5	7,8%	1	1,5%	6	4,6%
	Early withdrawal from the study, for others than efficacy reasons	1	1,6%	1	1,5%	2	1,5%
cBP	Inclusion criterion age violated	1	1,4%	1	1,4%	2	1,4%
	Non-permitted concomitant illness, relevant to efficacy	2	2,8%	1	1,4%	3	2,1%
	Non-permitted concomitant illness, not relevant to efficacy			2	2,8%	2	1,4%
	Non-permitted concomitant therapy or pretreatment not discontinued on time, relevant to efficacy	5	7,0%	4	5,6%	9	6,3%
	Serious postponement of study visit	3	4,2%	1	1,4%	4	2,8%
	Insufficient compliance	6	8,5%	2	2,8%	8	5,6%
	Early withdrawal from the study, (probably) for reasons of efficacy	3	4,2%	3	4,2%	6	4,2%
	Early withdrawal from the study, for others than efficacy reasons	2	2,8%			2	1,4%

Referred to the ability to remain in the P-P collective, more protocol violations occurred in the capsicum than in the placebo group resulting in a difference in the number of patients in PP. Investigators rated most of them as being due to insufficient compliance.

Gender (ITT)

		Capsicum		Placebo		Total	
Gender		N	%	N	%	N	%
Chronic soft tissue pain	male	32	50,0%	22	33,3%	54	41,5%
	female	32	50,0%	44	66,7%	76	58,5%
Chronic back pain with vertebral component	male	25	35,2%	24	33,8%	49	34,5%
	female	46	64,8%	47	66,2%	93	65,5%

Age (ITT)

		Capsicum		Placebo		Total	
Age [years]		N	%	N	%	N	%
Chronic soft tissue pain	18 - 25	4	6,3%	6	9,1%	10	7,7%
	26 - 35	9	14,1%	8	12,1%	17	13,1%
	36 - 45	11	17,2%	7	10,6%	18	13,8%
	46 - 55	16	25,0%	13	19,7%	29	22,3%
	56 - 65	22	34,4%	30	45,5%	52	40,0%
	66 - 71	1	1,6%	2	3,0%	3	2,3%
	81	1	1,6%			1	,8%
Chronic back pain with vertebral component	18 - 25	6	8,5%	3	4,2%	9	6,3%
	26 - 35	6	8,5%	7	9,9%	13	9,2%
	36 - 45	14	19,7%	23	32,4%	37	26,1%
	46 - 55	25	35,2%	12	16,9%	37	26,1%
	56 - 65	19	26,8%	24	33,8%	43	30,3%
	66 - 71			2	2,8%	2	1,4%
	81	1	1,4%			1	,7%

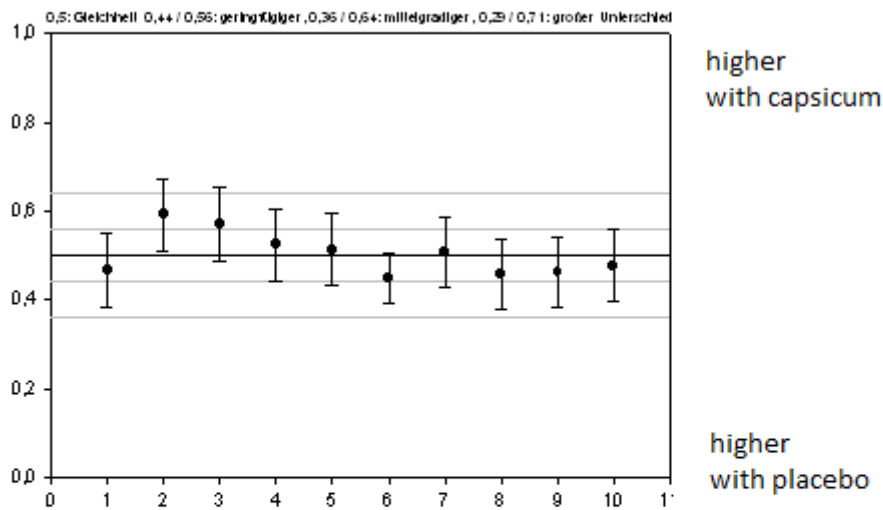
Demographic parameters (ITT)

Statistics			M	S	Min	Max	N
Chronic soft tissue pain	Capsicum	Age (Years)	48,88	13,97	19,0	81,0	64
		Height (cm)	169,97	9,43	150,0	192,0	64
		Weight (kg)	77,17	17,34	48,0	130,0	64
		BMI (kg/m2)	26,60	5,10	17,9	46,5	64
	Placebo	Age (Years)	49,85	14,02	19,0	67,0	66
		Height (cm)	166,94	7,82	154,0	182,0	66
		Weight (kg)	72,88	14,69	47,0	120,0	66
		BMI (kg/m2)	26,02	4,09	19,8	37,0	66
Chronic back pain with vertebral component	Capsicum	Age (Years)	48,07	12,62	19,0	81,0	71
		Height (cm)	170,49	8,25	149,0	196,0	71

Statistics			M	S	Min	Max	N
		Weight (kg)	76,14	14,10	52,0	124,0	71
		BMI (kg/m ²)	26,19	4,48	18,2	39,1	71
	Placebo	Age (Years)	48,44	12,12	23,0	68,0	71
		Height (cm)	167,97	8,00	152,0	188,0	71
		Weight (kg)	72,44	13,09	49,0	117,0	71
		BMI (kg/m ²)	25,69	4,52	19,4	40,5	71

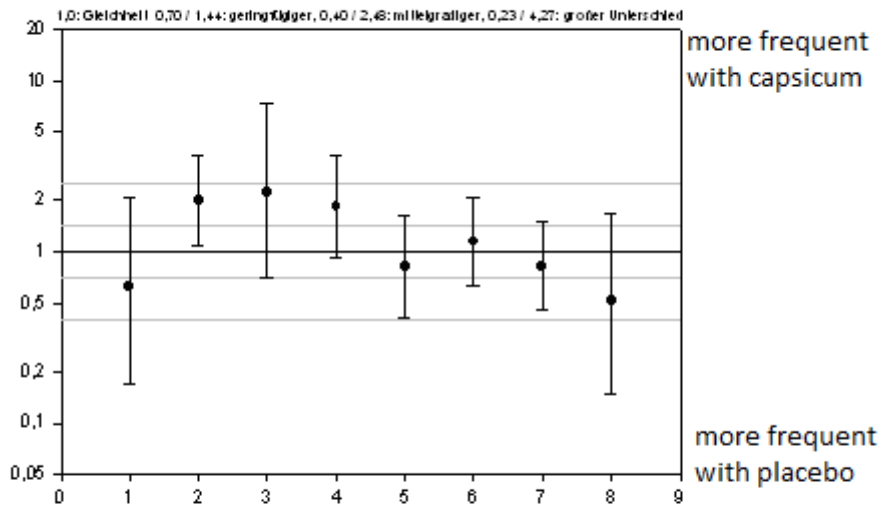
Chronic soft tissue pain

Between group comparability at enrolment. Part I: Metric variables.
Mann-Whitney statistic with 90% confidence interval.



- Kriterien:
- 1 - Lebensalter (Jahre)
 - 2 - Körpergröße (cm)
 - 3 - Körpergewicht (kg)
 - 4 - Body Mass Index (kg/m²)
 - 5 - Erkrankungsdauer (Monate)
 - 6 - Behandlungsdauer (Tage)
 - 7 - Intensität des Schmerzes zum Untersuchungszeitpunkt
 - 8 - Retrospektiv stärkste Schmerzintensität
 - 9 - Retrospektiv durchschnittliche Schmerzintensität
 - 10 - Schmerz-Summscore

Between group comparability on enrolment. Part II: Dichotomic variables.
Odds ratio with 90% confidence interval.



- Kriterien:
- 1 - According-to-protocol Kollektiv
 - 2 - Geschlecht männlich
 - 3 - Arbeitsunfähigkeit
 - 4 - Nichtmedikamentöse Vorbehandlung
 - 5 - Medikamentöse (analgetische) Vorbehandlung
 - 6 - Begleiterkrankung
 - 7 - Begleittherapie
 - 8 - Gute bis sehr gute Compliance

Main diagnosis (ITT)

		Capsicum		Placebo		Total	
ICD-10Code		N	%	N	%	N	%
cSTP	M35.3	1	1,6%			1	,8%
	M62.8	2	3,1%	5	7,6%	7	5,4%
	M65.4			3	4,5%	3	2,3%
	M65.8			2	3,0%	2	1,5%
	M65.9	2	3,1%	2	3,0%	4	3,1%
	M70.2			2	3,0%	2	1,5%
	M70.4	1	1,6%			1	,8%
	M71.9	2	3,1%			2	1,5%
	M75.0	14	21,9%	18	27,3%	32	24,6%
	M75.5	1	1,6%			1	,8%
	M75.8			2	3,0%	2	1,5%
	M76.5			1	1,5%	1	,8%
	M76.6			1	1,5%	1	,8%

		Capsicum		Placebo		Total	
ICD-10Code		N	%	N	%	N	%
	M76.8	1	1,6%			1	,8%
	M77.0			2	3,0%	2	1,5%
	M77.1	7	10,9%	2	3,0%	9	6,9%
	M77.2			1	1,5%	1	,8%
	M77.8	1	1,6%	1	1,5%	2	1,5%
	M77.9	5	7,8%	3	4,5%	8	6,2%
	M79.0	15	23,4%	11	16,7%	26	20,0%
	M79.1	12	18,8%	9	13,6%	21	16,2%
	M79.9			1	1,5%	1	,8%
cBP	M42.1	1	1,4%	1	1,4%	2	1,4%
	M47.2	8	11,3%	9	12,7%	17	12,0%
	M47.8			1	1,4%	1	,7%
	M53.1	7	9,9%	9	12,7%	16	11,3%
	M54.1	15	21,1%	8	11,3%	23	16,2%
	M54.2	8	11,3%	7	9,9%	15	10,6%
	M54.3	1	1,4%			1	,7%
	M54.4	6	8,5%	11	15,5%	17	12,0%
	M54.5	19	26,8%	20	28,2%	39	27,5%
	M54.6	2	2,8%			2	1,4%
	M54.8	1	1,4%			1	,7%
	M54.9	3	4,2%	5	7,0%	8	5,6%

Duration of complaints (ITT)

		Capsicum		Placebo		Total	
Duration of complaints		N	%	N	%	N	%
cSTP	≤ 2 Weeks	6	9,4%	2	3,0%	8	6,2%
	1 Month	13	20,3%	17	25,8%	30	23,1%
	2 - 3 Months	12	18,8%	13	19,7%	25	19,2%
	4 - 12 Months	8	12,5%	13	19,7%	21	16,2%

		Capsicum		Placebo		Total	
Duration of complaints		N	%	N	%	N	%
	>1 - 3 Years	7	10,9%	7	10,6%	14	10,8%
	>3 - 5 Years	7	10,9%	9	13,6%	16	12,3%
	>5 - 10 Years	4	6,3%	2	3,0%	6	4,6%
	>10 (- 45) Years	7	10,9%	3	4,5%	10	7,7%
cBP	≤ 2 Weeks	2	2,8%	6	8,5%	8	5,6%
	1 Month	14	19,7%	9	12,7%	23	16,2%
	2 - 3 Months	10	14,1%	7	9,9%	17	12,0%
	4 - 12 Months	11	15,5%	10	14,1%	21	14,8%
	>1 - 3 Years	7	9,9%	11	15,5%	18	12,7%
	>3 - 5 Years	10	14,1%	11	15,5%	21	14,8%
	>5 - 10 Years	12	16,9%	14	19,7%	26	18,3%
	>10 (- 45) Years	5	7,0%	3	4,2%	8	5,6%

Pain sites on the body diagram (ITT; more than one entry possible per patient).

	Chronic soft tissue pain						Chronic back pain					
	Capsicum		Placebo		Gesamt		Capsicum		Placebo		Gesamt	
Lokalization	N	%	N	%	N	%	N	%	N	%	N	%
7,08	1	1,6%	1	1,5%	2	1,5%			1	1,4%	1	,7%
8,05	1	1,6%	1	1,5%	2	1,5%						
8,06			1	1,5%	1	,8%	2	2,8%			2	1,4%
8,07	1	1,6%	1	1,5%	2	1,5%			2	2,8%	2	1,4%
8,08	4	6,3%	1	1,5%	5	3,8%	4	5,6%	4	5,6%	8	5,6%
8,09	1	1,6%			1	,8%	1	1,4%	1	1,4%	2	1,4%
8,10			5	7,6%	5	3,8%	4	5,6%	2	2,8%	6	4,2%
8,11			1	1,5%	1	,8%						
8,20	2	3,1%			2	1,5%						
8,21			3	4,5%	3	2,3%	1	1,4%			1	,7%
8,22							1	1,4%	1	1,4%	2	1,4%
8,23									2	2,8%	2	1,4%
8,25									1	1,4%	1	,7%

	Chronic soft tissue pain						Chronic back pain					
	Capsicum		Placebo		Gesamt		Capsicum		Placebo		Gesamt	
Lokalisation	N	%	N	%	N	%	N	%	N	%	N	%
8,26	2	3,1%	1	1,5%	3	2,3%						
9,04	1	1,6%	1	1,5%	2	1,5%						
9,05	2	3,1%	2	3,0%	4	3,1%						
9,06	1	1,6%	2	3,0%	3	2,3%			1	1,4%	1	,7%
9,08	1	1,6%			1	,8%	2	2,8%	1	1,4%	3	2,1%
9,09			2	3,0%	2	1,5%	2	2,8%	2	2,8%	4	2,8%
9,10	1	1,6%	2	3,0%	3	2,3%	1	1,4%	3	4,2%	4	2,8%
9,11	8	12,5%	7	10,6%	15	11,5%						
9,12	1	1,6%			1	,8%						
9,20	6	9,4%	1	1,5%	7	5,4%						
9,21	3	4,7%	2	3,0%	5	3,8%						
9,26	2	3,1%			2	1,5%						
9,27	1	1,6%	3	4,5%	4	3,1%						
10,05			2	3,0%	2	1,5%						
10,06			1	1,5%	1	,8%						
10,07			1	1,5%	1	,8%						
10,08							3	4,2%			3	2,1%
10,09			2	3,0%	2	1,5%						
10,10	1	1,6%			1	,8%						
10,20			1	1,5%	1	,8%						
10,27	1	1,6%	1	1,5%	2	1,5%						
11,09	1	1,6%			1	,8%						
12,04			1	1,5%	1	,8%						
12,07	1	1,6%			1	,8%						
12,08			1	1,5%	1	,8%	2	2,8%	1	1,4%	3	2,1%
12,09	2	3,1%			2	1,5%						
12,12			1	1,5%	1	,8%						
12,20			1	1,5%	1	,8%						
12,27			1	1,5%	1	,8%						
13,07	1	1,6%			1	,8%						
13,13			1	1,5%	1	,8%						
13,27			1	1,5%	1	,8%						

	Chronic soft tissue pain						Chronic back pain					
	Capsicum		Placebo		Gesamt		Capsicum		Placebo		Gesamt	
Lokalisation	N	%	N	%	N	%	N	%	N	%	N	%
14,04	2	3,1%	1	1,5%	3	2,3%						
14,07			1	1,5%	1	,8%						
14,08							2	2,8%	2	2,8%	4	2,8%
14,09			1	1,5%	1	,8%			1	1,4%	1	,7%
14,12	2	3,1%	2	3,0%	4	3,1%						
14,13	1	1,6%	1	1,5%	2	1,5%						
14,19	2	3,1%	1	1,5%	3	2,3%						
15,03	1	1,6%			1	,8%						
15,07	1	1,6%			1	,8%	2	2,8%	1	1,4%	3	2,1%
15,08	8	12,5%	8	12,1%	16	12,3%	18	25,4%	15	21,1%	33	23,2%
15,09	1	1,6%			1	,8%	2	2,8%	1	1,4%	3	2,1%
15,10	1	1,6%			1	,8%						
15,12	1	1,6%			1	,8%						
15,13	1	1,6%	1	1,5%	2	1,5%						
15,19	1	1,6%	2	3,0%	3	2,3%						
15,28	2	3,1%			2	1,5%						
16,07			1	1,5%	1	,8%	4	5,6%	3	4,2%	7	4,9%
16,08	4	6,3%	2	3,0%	6	4,6%	11	15,5%	16	22,5%	27	19,0%
16,09			1	1,5%	1	,8%	1	1,4%	2	2,8%	3	2,1%
16,26			1	1,5%	1	,8%						
16,28			1	1,5%	1	,8%						
17,07									2	2,8%	2	1,4%
17,08			1	1,5%	1	,8%	9	12,7%	9	12,7%	18	12,7%
17,09									1	1,4%	1	,7%
17,18			1	1,5%	1	,8%						
17,19			1	1,5%	1	,8%						
17,28	1	1,6%			1	,8%						
18,03	1	1,6%	1	1,5%	2	1,5%						
18,06			1	1,5%	1	,8%						
18,08			1	1,5%	1	,8%	3	4,2%	2	2,8%	5	3,5%
18,10			1	1,5%	1	,8%						
18,11			1	1,5%	1	,8%						

	Chronic soft tissue pain						Chronic back pain					
	Capsicum		Placebo		Gesamt		Capsicum		Placebo		Gesamt	
Lokalization	N	%	N	%	N	%	N	%	N	%	N	%
18,13	1	1,6%	2	3,0%	3	2,3%						
18,18	1	1,6%			1	,8%						
18,19			1	1,5%	1	,8%						
18,20			1	1,5%	1	,8%						
18,26			1	1,5%	1	,8%						
18,29			1	1,5%	1	,8%						
19,22	1	1,6%			1	,8%						
19,26	1	1,6%			1	,8%						
20,06	1	1,6%			1	,8%						
20,10	2	3,1%			2	1,5%						
20,13	1	1,6%			1	,8%						
20,26	1	1,6%			1	,8%						
21,05	1	1,6%			1	,8%						
24,24			1	1,5%	1	,8%						
25,25	1	1,6%			1	,8%						
28,10	1	1,6%			1	,8%						
28,22	1	1,6%			1	,8%						
29,10	1	1,6%			1	,8%						
31,09			1	1,5%	1	,8%						
31,23	1	1,6%			1	,8%						
31,25	1	1,6%			1	,8%						
32,07	1	1,6%			1	,8%						
32,09	1	1,6%			1	,8%						

Size of painful area [cm²] at inclusion (ITT)

Statistics	Chronic soft tissue pain			Chronic back pain		
	Capsicum	Placebo	Total	Capsicum	Placebo	Total
Mean	269,41	272,17	270,81	342,24	357,51	349,87
SDev	235,50	304,23	271,53	365,38	343,82	353,59
Min	16	12	12	25	16	16
Max	1200	1600	1600	1800	1600	1800

5%-Perzentil	25,0	25,0	25,0	46,0	38,4	41,4
I. Q	100,0	95,3	100,0	100,0	100,0	100,0
Median	200,0	150,0	190,0	200,0	225,0	200,0
III. Q	400,0	400,0	400,0	500,0	600,0	600,0
95%-Perzentil	656,3	1095,0	845,0	1020,0	960,0	900,0
N	64	66	130	71	71	142

Prior non-drug treatment of the soft tissue rheumatic pain. (ITT; more than one mention possible per patient)

	Chronic soft tissue pain						Chronic back pain					
	Capsicum		Placebo		Total		Capsicum		Placebo		Total	
TYPE OF THERAPY	N	%	N	%	N	%	N	%	N	%	N	%
Massages	8	12,5%	5	7,6%	13	10,0%	8	11,3%	9	12,7%	17	12,0%
Fango	3	4,7%	4	6,1%	7	5,4%	1	1,4%	1	1,4%	2	1,4%
Acupuncture	2	3,1%	1	1,5%	3	2,3%	1	1,4%			1	,7%
Heat treatment	1	1,6%			1	,8%			2	2,8%	2	1,4%
Medicinal baths							1	1,4%			1	,7%
Electrotherapy	3	4,7%	5	7,6%	8	6,2%	5	7,0%	7	9,9%	12	8,5%
Kinesitherapy	5	7,8%	2	3,0%	7	5,4%	5	7,0%	3	4,2%	8	5,6%
Microwave	3	4,7%	1	1,5%	4	3,1%	3	4,2%	2	2,8%	5	3,5%
Ultrasound	2	3,1%	1	1,5%	3	2,3%						
Massage of connective tissue	2	3,1%			2	1,5%	1	1,4%	1	1,4%	2	1,4%
Cooling with ice	1	1,6%			1	,8%						
Physical therapy, not specified									1	1,4%	1	,7%
Back awareness training							1	1,4%			1	,7%
Stretching therapy	1	1,6%			1	,8%						

Prior non-drug treatment of the soft tissue rheumatic pain (ITT; more than one mention possible per patient)

	Chronic soft tissue pain						Chronic back pain					
	Capsicum		Placebo		Total		Capsicum		Placebo		Total	
Number	N	%	N	%	N	%	N	%	N	%	N	%
0	44	68,8%	53	80,3%	97	74,6%	50	70,4%	48	67,6%	98	69,0%
1	11	17,2%	8	12,1%	19	14,6%	17	23,9%	20	28,2%	37	26,1%
2	7	10,9%	4	6,1%	11	8,5%	3	4,2%	3	4,2%	6	4,2%
3	2	3,1%	1	1,5%	3	2,3%	1	1,4%			1	,7%

Number of prior drug therapies per patient (ITT)

	Chronic sft tissue pain						Chronic back pain					
	Capsicum		Placebo		Total		Capsicum		Placebo		Total	
Number	N	%	N	%	N	%	N	%	N	%	N	%
0	49	76,6%	48	72,7%	97	74,6%	47	66,2%	50	70,4%	97	68,3%
1	10	15,6%	15	22,7%	25	19,2%	16	22,5%	18	25,4%	34	23,9%
2	4	6,3%	1	1,5%	5	3,8%	7	9,9%	2	2,8%	9	6,3%
3	1	1,6%	1	1,5%	2	1,5%	1	1,4%	1	1,4%	2	1,4%
4			1	1,5%	1	,8%						

Prior drug treatments had been used by 25.4 % of patients in the cSTP collective (verum: 23.4 %; placebo: 27.3 %) and 31.7% in the cBP collective (verum: 33.8 %; placebo: 29.6 %). The majority were anti-inflammatory agents of the anthranilic-/arylacetic acid and arypropionic acid derivatives type in the treatment groups of both collectives. With few exceptions, such treatments, depending on type or substance class, were stopped sufficiently in advance of the study to be in accordance with protocol. No relevant between-group difference in the frequency of drug treatments has been observed.

Sick leave due to pain at inclusion (ITT)

		Capsicum		Placebo		Total	
sick leave / duration (days)		N	%	N	%	N	%
Chronic soft tissue pain	No	56	87,5%	62	93,9%	118	90,8%
	1	5	7,8%	3	4,5%	8	6,2%
	2	1	1,6%			1	,8%
	4			1	1,5%	1	,8%

	5	1	1,6%			1	,8%
	23	1	1,6%			1	,8%
Chronic back pain	No	67	94,4%	64	90,1%	131	92,3%
	1	1	1,4%	4	5,6%	5	3,5%
	3			1	1,4%	1	,7%
	4			1	1,4%	1	,7%
	5	1	1,4%	1	1,4%	2	1,4%
	8	1	1,4%			1	,7%
	28	1	1,4%			1	,7%

Concomitant diseases per patient (ITT)

	Chronic soft tissue pain						Chronic back pain					
	Capsicum		Placebo		Total		Capsicum		Placebo		Total	
Number	N	%	N	%	N	%	N	%	N	%	N	%
0	26	40,6%	29	43,9%	55	42,3%	31	43,7%	34	47,9%	65	45,8%
1	14	21,9%	15	22,7%	29	22,3%	15	21,1%	14	19,7%	29	20,4%
2	10	15,6%	7	10,6%	17	13,1%	10	14,1%	8	11,3%	18	12,7%
3	7	10,9%	7	10,6%	14	10,8%	8	11,3%	8	11,3%	16	11,3%
4	4	6,3%	4	6,1%	8	6,2%	4	5,6%	6	8,5%	10	7,0%
5	3	4,7%	3	4,5%	6	4,6%	3	4,2%	1	1,4%	4	2,8%
8			1	1,5%	1	,8%						

Patient compliance evaluated by the investigator (ITT; some data missing because of drop-outs)

		Capsicum		Placebo		Total		
Evaluation		N	%	N	%	N	%	
Chronic soft tissue pain	Visit 2	No information	1	1,6%			1	,8%
		Excellent	37	57,8%	44	66,7%	81	62,3%
		Good	23	35,9%	20	30,3%	43	33,1%
		Satisfactory	2	3,1%	2	3,0%	4	3,1%
		Bad	1	1,6%			1	,8%
	Visit 3	No information	2	3,1%	1	1,5%	3	2,3%
		Excellent	38	59,4%	46	69,7%	84	64,6%
		Good	18	28,1%	17	25,8%	35	26,9%

			Capsicum		Placebo		Total	
Evaluation			N	%	N	%	N	%
		Satisfactory	5	7,8%	2	3,0%	7	5,4%
		Bad	1	1,6%			1	,8%
	Visit 4	No information	5	7,8%	2	3,0%	7	5,4%
		Excellent	37	57,8%	47	71,2%	84	64,6%
		Good	19	29,7%	14	21,2%	33	25,4%
		Satisfactory	3	4,7%	3	4,5%	6	4,6%
Chronic back pain	Visit 2	Excellent	49	69,0%	42	59,2%	91	64,1%
		Good	16	22,5%	27	38,0%	43	30,3%
		Satisfactory	5	7,0%	2	2,8%	7	4,9%
		Bad	1	1,4%			1	,7%
	Visit 3	No information	1	1,4%	1	1,4%	2	1,4%
		Excellent	44	62,0%	41	57,7%	85	59,9%
		Good	20	28,2%	28	39,4%	48	33,8%
		Satisfactory	5	7,0%			5	3,5%
		Bad	1	1,4%	1	1,4%	2	1,4%
	Visit 4	No information	4	5,6%	2	2,8%	6	4,2%
		Excellent	46	64,8%	42	59,2%	88	62,0%
		Good	18	25,4%	26	36,6%	44	31,0%
		Satisfactory	3	4,2%			3	2,1%
		Bad			1	1,4%	1	,7%