

# STUDY TO EVALUATE THE EFFECTIVENESS OF A TRANS<sup>DERMAL</sup> IBUPROFEN CREAM FOR THE RELIEF OF PAIN<sup>1</sup>

## Study Design

The study was a double blind, placebo controlled trial. Subjects were given either active cream or placebo cream at the start of the study. They used the cream three times per day for one week. They then used nothing for a week. They then used the cross-over cream three times per day for a week. During use of the cream the subjects kept diaries where they recorded their pain level before and after each use on a pain scale of 1 to 10 with 10 being the worst pain.

## Study Subjects

The study enrolled 19 subjects. Of these 18 completed the study. One was dropped from the study due to illness. Of the 18 who completed the study there were 13 females and 5 males.

The subjects all had joint pain. Of the subjects 9 had knee pain, 3 had hip pain, 2 had wrist pain and one each had shoulder, elbow, foot and thumb pain.

## Results

Pain scores were compared between starting value at the beginning of the week of cream use with final value at the end of the week. The change in pain score was calculated and compared by paired test.

At the start of the use of each cream there was no statistical difference in the pain scores between the active ibuprofen cream week and the placebo cream week. The

initial pain score in the active ibuprofen cream week was 5.5 +/- 1.6 units and the initial pain score in the placebo cream week was 4.9 +/- 1.4 units.

The mean change in pain score in the active ibuprofen cream group was -3.2 +/- 1.6 units and the mean change pain score in the placebo cream group was -1.2 +/- 1.8 units. Using the paired t test the 2-tailed p was 0.0003.

The results are depicted in the attached table on the next page. Each subject is recorded on the graph as a line

running from the initial pain score at the start of the use of the cream and running to the pain score after use for one week. As each subject used both active and placebo for one week each with a week in between where no cream was used, each subject is

represented by one line in each of the active and placebo side of the graph. A table is also included tabulating the pain scores. This table gives

the reader an opportunity to see the corresponding pain scores for active and placebo in each individual subject.

## Summary

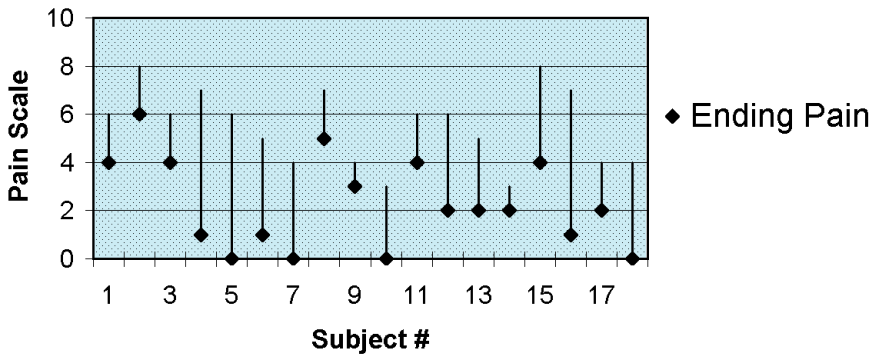
When compared to placebo the active transdermal ibuprofen cream proved highly statistically superior with  $p=0.0003$ . No adverse events were recorded in the study and no skin irritation was observed. ●

## IBUPROFEN CLINICAL STUDY

<sup>1</sup> Study conducted by SMG Research LLC of Salt Lake City, UT for Strategic Science & Technologies, LLC, Cambridge, MA. Completed December 2005.

IBUPROFEN CLINICAL STUDY CONTINUED

**IBUPROFEN--ACTIVE**  
Starting & Ending Pain. N = 18.



Subject #	ACTIVE		
	Before	One Week	Ending Pain
1	6	4	4
2	8	6	6
3	6	4	4
4	7	1	1
5	6	0	0
6	5	1	1
7	4	0	0
8	7	5	5
9	4	3	3
10	3	0	0
11	6	4	4
12	6	2	2
13	5	2	2
14	3	2	2
15	8	4	4
16	7	1	1
17	4	2	2
18	4	0	0

**PLACEBO**

Subject #	Before	One Week	Ending Pain
1	5	5	5
2	7	8	8
3	4	5	5
4	6	1	1
5	7	4	4
6	4	3	3
7	6	7	7
8	5	4	4
9	3	3	3
10	3	1	1
11	3	3	3
12	6	2	2
13	5	3	3
14	3	1	1
15	6	8	8
16	7	5	5
17	5	2	2
18	4	2	2

**IBUPROFEN--PLACEBO**  
Starting & Ending Pain. N = 18.

