

COMPREHENSIVE REPORT OF ALL PATIENTS TREATED WITH MAGNETIC THERAPY IN WATERBURY FROM JANUARY 8, TO SEPTEMBER 17, 1990

On January 8, 1990, pursuant to the St. Mary's Hospital, I.R.B. approved protocol, #12-89, dated October 4, 1989, we began entering patients into a randomized, double-blind placebo controlled magnetic therapy treatment study.

On September 17, 1990, our records identify 245 patient- joints, entered into magnetic therapy treatment studies, that have either completed a course, of usually 18 treatments, or who are in the process of completing their 18 treatment plan, or who dropped out of the study.

From January 8, thru June 12, 1990, a total of 142 patients were given magnetic therapy treatment at 133 Scovill Street, Suite 306. Initially, an observational study of 13 patients with chronic and/or persistent disease was conducted. The 13 patients included family and friends of the investigators and several physicians from St. Mary's Hospital. Further, a total of 102 patients were entered into a randomized, double-blind placebo controlled study. Additionally, a total of 27 patients were entered into an open crossover study of non-responding patients from the double-blind controlled study. The 102 patient, double-blind study was conducted in two phases, the first being a 50 patient-joint study and the second being a 52 patient-joint study.

IN SUMMARY, WE CONDUCTED THE FOLLOWING STUDIES:

OPEN PILOT STUDY	n = 13 }
DOUBLE-BLIND PHASE I:	n = 50 } n = 142
DOUBLE-BLIND PHASE II:	n = 52 }
OPEN CROSSOVER STUDY, OLD:	n = 27 }

On June 13, 1990, the site of the magnetic therapy treatment studies moved to; 88 Union Street, Waterbury, known as the Magnetic Therapy Center (MTC).

On June 18, 1990, the randomized, double-blind placebo controlled study II, of rheumatic appendages commenced, and patient #1 was entered. Dr.'s A.J. Bollet and David Trock are the blinded investigators conducting this study, in progress. The guidance counselor for the F.D.A., Washington D.C., has suggested that 120 patients be treated and evaluated in this randomized double-blind controlled study.

To date, 31 patients have been entered into this study. Several patients have completed the study and their final evaluation has been completed. Dr.'s Bollet and Trock review and evaluate the patients weekly at the Center in Waterbury.

Additionally, 31 patients who did not have persistent and chronic arthritic symptoms greater than one year duration or did not qualify for entry into the double-blind study, have been entered into an observational study of rheumatic appendages. Furthermore, 36 patients have been entered into an observational study of the effects of magnetic therapy treatment of back pain and neck pain, pursuant to the St.Mary's Hospital I.R.B. approved protocol # 06-90 dated May 30, 1990. In addition, 5 patients have been entered into an open crossover study for non-responding, placebo treated patients from the randomized, double-blind controlled study.

IN SUMMARY, THE FOLLOWING STUDIES ARE NOW IN PROGRESS:

DOUBLE BLIND II: n = 31 } OBSERVATIONAL ARMS/LEGS: n = 31 } n = 103
 OPEN STUDY BACK & NECK: n = 36 }
 OPEN CROSSOVER STUDY, NEW: n = 5 }

Copies of the original hand written patient listings of all eight studies are available upon request. The approved randomization codes, were registered with Dr. Alvan R. Feinstein M.D., Yale University School of Medicine.

MAGNETIC THERAPY TREATMENT RESPONSE RATINGS

The following Overall Response Ratings were employed, based on a Final Evaluation Key, developed with St. Mary's physicians & completed at the concluding patient evaluation:

- None: = Absence of therapeutic response.
- Slight: = Fair, unacceptable, minimal response.
- Improved: = Good, short of best possible.
- Definite: = Best possible, considering - stage of disease.

All 142 patients treated from January 8, to June 12, 1990, had at least five (5) evaluations; Baseline, Two Week Follow/Up, Four Week Follow/up, Final, and Two Week After Treatment evaluation.

The 103 patients treated or presently in treatment, from June 18, to date, are scheduled for at least four (4) evaluations, Baseline, Midway, Final and One Month After Treatment. An appropriate Final Evaluation Key is completed. From magnetic therapy study begin, January 8, 1990 to date, there have been no adverse reactions experienced or reported by any patient during or after magnetic therapy.

MAGNETIC THERAPY STUDIES RESPONSE REPORT

OPEN PILOT STUDY: n = 13.
 FINAL RATINGS

- Definite = 8
- Improved = 1
- Slight = 3
- None = 1

DOUBLE-BLIND PHASE I: n = 50.
 FINAL RATINGS

ACTIVE TREATMENT		PLACEBO TREATMENT	
Definite	= 18	Definite	= 4
Improved	= 2	Improved	= 2
Slight	= 2	Slight	= 3
None	= 1 (Comp. Case)	None	= 15
SUBTOTAL	23	SUBTOTAL	24
Dropouts	= 2	Dropouts	= 1
TOTAL	25	TOTAL	25

Dr. Alvan R. Feinstein M.D. evaluation report concluded:

"This comparison is highly statistically significant, no matter how it is expressed. I would cite it as the total of improved and definite ratings per total of analyzed ratings. With this citation, the comparison is 20/23 (87%) vs. 6/24 (25%). The value of X² is 18.2 with P<.001." Quote from May 22, 1990 letter from Dr. Alvan R. Feinstein M.D. page 2.

DOUBLE-BLIND PHASE II: = n = 52.

TO DATE ONLY 36 CASE REPORT FORMS HAVE BEEN RETURNED FROM THE OFFICE OF THE EVALUATOR, WHERE THE CHARTS WERE HELD FOR "SOURCE DOCUMENTATION", AND MANUAL STATISTICAL TABULATION. THESE ARE THE FINAL RATINGS OF THE 36 CHARTS NOW AVAILABLE.

ACTIVE TREATMENT		PLACEBO TREATMENT	
Definite	= 12	Definite	= 6
Improved	= 0	Improved	= 0 *
Slight	= 0	Slight	= 0 *
None	= 4	None	= 10
SUBTOTAL	= 16	SUBTOTAL	= 16
Dropouts	= 3	Dropouts	= 1
TOTAL	= 19	TOTAL	= 17

The following statistical evaluation was completed based on a conference and supervision by the St. Mary's Hospital, Dept. of Epidemiology, concerning; CHI-Square test values.

ACTIVE: 12/16 = (75%) PLACEBO: 6/16 = (37%)

X² = E (O - E)² / E.

X² = 4.56; P value was determine to be between .05 and .01.

OPEN CROSSOVER STUDY, OLD: n = 27

FINAL RATINGS

Definite	= 11
Improved	= 5
Slight	= 5
None	= 6

DOUBLE-BLIND II: n = 31.

This study is presently in progress. The Case Report Forms are open for inspection by the St. Mary's I.R.B..

OBSERVATIONAL ARMS/LEGS: n = 31.

This study is presently in progress. Approximately 50% of the patients have concluded their planned treatment schedule and have been evaluated at least four times. Initial analysis of the results indicates an overwhelming majority of the patients have a Definite Response. These charts are open to I.R.B. audit.

OPEN STUDY; BACK AND NECK: n = 36.

This study is presently in progress. Approximately 50% of the patients have concluded their planned treatment schedule and have been evaluated at least four times. The patients have predominantly reported positive and dramatic improvement, rated as a Definite Response. These observations have been tabulated and recorded by our nursing staff. Effective today, we

have a second, more refined, back and neck magnetic therapy delivery system in operation, which does not have patient weight limitations.

OPEN CROSSOVER STUDY, NEW: n = 5

These five patients were entered into the Open Cross Over Study within the past two to three weeks, and therefore there is no data at this point in time.

Should any aspect of the studies carried out during the first year require greater clarification, I would be delighted to elaborate as specifically requested.

Please accept this summary report as an initial preliminary communication. We, therefore make application for an extension of the Institutional Review Board approval, for all the magnetic therapy protocols, for one additional year.

Sincerely,

Richard Markoll M.D. Waterbury, September 17, 1990