

Efficacy and Safety of Low Level Electromagnetic Fields Treatment in Parkinson's Disease

O. Klepitskaya, University of Colorado Health Sciences Center, Aurora, Colorado

R. Kumar, Colorado Neurological Institute Movement Disorder Center, Englewood, Colorado

BACKGROUND

1990s. Early experiments suggested that utilization of extremely weak magnetic fields (EMF) may impact signs or symptoms of several major neurological disorders (e.g. Epilepsy, Parkinson's Disease, Alzheimer's).

2003. Further clinical observations by Dr. Jerry Jacobson suggested that EMF fields applied by a specially created device (Resonator) appeared to ameliorate a number of the signs and symptoms associated with Parkinson's disease (PD).

2007. The first open label pilot study in PD.
 • 13 subjects
 • 3 weeks (3 treatments a week)
 • Conclusion: EMF treatment with the Resonator may have beneficial effects as determined by the scores:

Change	Base	3 weeks	%
UPDRS II	13.92+/-4.59	6.77+/-3.42	-51%
UPDRS III	32.46+/-10.09	21.08+/-8.83	-35%
PDQ39 SI	24.75+/-12.85	18.81+/-14.47	-24%

OBJECTIVE

To conduct a pilot study to demonstrate the efficacy of the Resonator, a non invasive device, utilizing targeted low level EMF as an adjuvant therapy for symptomatic relief of PD symptoms.

METHODS

* double-blind, randomized, placebo controlled

* adjuvant to standard medical therapy

* PD patients with motor fluctuations

* 12 subjects (6 per group)

* Intervention: 1.5hrs, 3 treatments a week, 8 weeks

* Standardized motor and non-motor assessments at baseline, 8 weeks, and monthly during 3 month washout period.



RESULTS

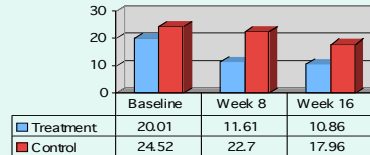
The treatment group demonstrated significant improvement over placebo after 8 weeks (endpoint) of therapy in the scales listed below.*

Significantly, improvement on several scales persisted up to 2 months (week 16) post treatment.

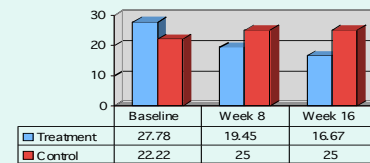
No treatment related adverse events reported.

*In all results p < 0.05, except for UPDRS III p= 0.054 and Finger Taps OFF p= 0.108.

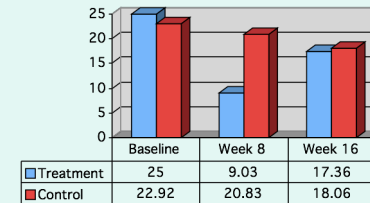
PDQ 39 Single Index



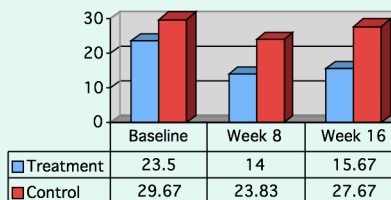
PDQ39B.Discomfort



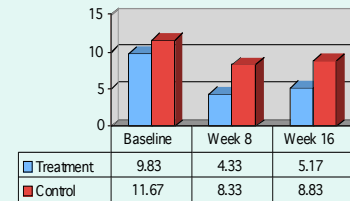
PDQ39 ADL



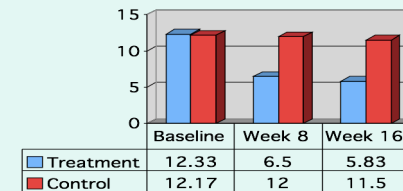
UPDRS: Motor (III)



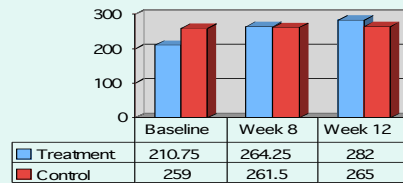
UPDRS: ADL (II)



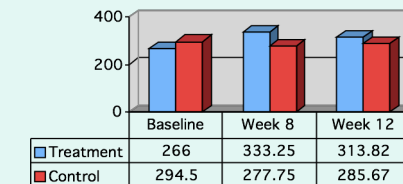
Beck Depression II



Finger Taps: OFF



Finger Taps: ON



The following tests were also used but showed little or no difference:

- Fatigue Severity Scale (FSS)
- Epworth Sleepiness Scale (ESS)
- Pittsburgh Sleep Quality Index (PSQI)
- Increase in "On" time as measured by diaries
- Penn. Smell Identification Test
- PDQ 39 subscales: Stigma, Social, Comm. Steps x Seconds test

MECHANISM

The precise mechanism of operation is unknown, but analogous to magnetic resonance imaging (MRI), the Resonator applies an external magnetic field to alter molecular or atomic targets in the body to achieve its results.

The field strengths used by the Resonator are in orders of magnitude below those utilized in MRI scanners, transcranial magnetic stimulators (TMS) and even well below that of the earth.

	Tesla	Gauss
MRI	0.1- 4	1,000-40,000
rTMS or TMS	0.1- 2	1,000-20,000
bar magnet	0.01-0.03	100-300
Earth's Field	5x10 ⁻⁵	0.5
Human Brain	5x10 ⁻¹²	0.00000005

Resonator 5x10⁻¹² 0.00000005

The Resonator utilizes a field strength and frequency that specifically focuses on target molecules associated with a disease. Various neurotrophic factors (brain derived neurotrophic factor, neurturin, glial derived neurotrophic factor) are considered to be the candidate target molecules for the magnetic fields and frequencies applied for the treatment of PD.

CONCLUSIONS

Low level EMF may improve motor and non-motor features of PD beyond that achieved with standard medical therapy. These effects are long-lasting. Larger placebo-controlled studies should be undertaken to confirm and further investigate the benefit of this unique, non invasive and potentially promising therapy.

FUTURE DIRECTIONS

Q4 of 2008 Sponsor will begin enrolment in a large pivotal phase III randomized, placebo controlled clinical trial, utilizing the PDQ-39 SI as its primary outcome measure.

REFERENCES

- *Saxena A., Jacobson J., Yamanaishi W., Scherlag B., Lamberth J., Saxena B. A hypothetical mathematical construct explaining the mechanism of biological amplification in experimental model utilizing pica Tesla (PT) electromagnetic fields. Medical hypotheses, 2003 60 (6), 621-639.
- *Scherlag BJ., Yamanaishi WS., Yuemei H., Jacobson JJ., Jackman WM., Lazzara R., Magnelsen and Cardiac Arrhythmias.Cardiology in Review March/April 2004 12(2): 85-96.
- *Sandyk R. Successful treatment of multiple sclerosis with magnetic fields. International Journal of Neuroscience. 1992; 66:237-250.
- *Cohen D. Detection of the brain's electrical activity with a superconducting magnetometer. Science 1972;175:664.