



# Evaluation of pulsing magnetic field effects on paresthesia in multiple sclerosis patients, a randomized, double-blind, parallel-group clinical trial



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## ABSTRACT

**Objectives:** Evidence is mounting that magnet therapy could alleviate the symptoms of multiple sclerosis (MS). This study was performed to test the effects of the pulsing magnetic fields on the paresthesia in MS patients.

**Patients and methods:** This study has been conducted as a randomized, double-blind, parallel-group clinical trial during the April 2012 to October 2013. The subjects were selected among patients referred to MS clinic of Imam Reza Hospital; affiliated to Kermanshah University of Medical Sciences, Iran. Sixty three patients with MS were included in the study and randomly were divided into two groups, 35 patients were exposed to a magnetic pulsing field of 4 mT intensity and 15-Hz frequency sinusoidal wave for 20 min per session 2 times per week over a period of 2 months involving 16 sessions and 28 patients was exposed to a magnetically inactive field (placebo) for 20 min per session 2 times per week over a period of 2 months involving 16 sessions. The severity of paresthesia was measured by the numerical rating scale (NRS) at 30, 60 days. The study primary end point was NRS change between baseline and 60 days. The secondary outcome was NRS change between baseline and 30 days.

**Results:** Patients exposing to magnetic field showed significant paresthesia improvement compared with the group of patients exposing to placebo.

**Conclusion:** According to our results pulsed magnetic therapy could alleviate paresthesia in MS patients. But trials with more patients and longer duration are mandatory to describe long-term effects.

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## 1. Introduction

Multiple sclerosis is a chronic inflammatory debilitating disease of central nervous system (CNS) that mainly affecting subjects aged between 15 and 50 years. It has severe impact on patients and their families. Paresthesia is one of the most common presenting symptoms in Multiple Sclerosis [1,2]. About 40% of the patients reported that such symptoms had a serious adverse effect on daily activities. Painful Paresthesia leads to avoidance of any triggering activities [3]. Since it can have significant impact on quality of life,

it needs to be treated appropriately. Medications that are used to treat paresthesia include carbamazepine, gabapentine and three cyclic anti-depressants [4].

Pharmacologic or rehabilitative treatments can treat MS symptoms such as paresthesia, spasticity and fatigue to a variable extent but management is quiet not ideal; therefore, the development of more effective symptomatic therapies remains a critical objective of MS care [5]. Patients with MS are widely using complementary and alternative medicine treatments, similarly to patients with other chronic diseases, yet the data concerning their effectiveness and safety is limited [5]. Pulsed electromagnetic field therapy (PEMFT), is a restorable technique most commonly used in the field of orthopedics for the treatment of non-union fractures, failed fusions, congenital pseudarthrosis and also for wound healing acceleration, alleviation of pain [6]. A large number of scientific and

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**Table 1**  
Baseline demographic and clinical characteristics.

Baseline characteristics	magnet group	placebo group	Total	P-value
Age (year) (Means $\pm$ SD)	37.88 $\pm$ 9.59	39.65 $\pm$ 10.67	38.52 $\pm$ 9/93	0.53
Female, N (%)	24(68.6)	16(64)	40(66.7)	0.58
Duration of disease (years) (Means $\pm$ SD)	10.31 $\pm$ 6.14	6.94 $\pm$ 5.12	9.14 $\pm$ 5.97	0.059
NRS(Means $\pm$ SD)	5.63 $\pm$ 1.96	5.45 $\pm$ 1.31	5.54 $\pm$ 1.63	0.38

SD: standard deviation.

clinical studies reporting that PEMFT help in bone unification, the reduction of pain, edema, and inflammation, and increasing blood circulation and stimulating the immune and endocrine systems [6]. Previous results revealed that Magnet therapy could alleviate the symptoms of MS, but that the effects were modest and required further confirmation [7]. The mechanisms by which magnets might relieve MS symptoms have not been conclusively identified or proven. Previous studies have shown electromagnetic field effects on CNS in the following areas: [1] altered calcium transport across cellular membranes –which may facilitate axonal conduction in brain damage caused by demyelination, [2] altered release of melatonin from the pineal gland, and [3] local or loco regional immunomodulatory action [8]. Although there have already been several anecdotal positive reports of effect of electromagnetic field on MS symptoms, no placebo controlled, double-blinded study is currently available in the literature investigated the effect of electromagnetic fields on MS paresthesia. This study was performed to test the effects of the pulsing magnetic fields on the paresthesia in MS patients.

## 2. Methods

This study was performed as a randomized, double-blind, parallel-group clinical trial during the April 2012 to October 2013. Patients with clinically definite MS who were admitted to outpatient MS clinic of Imam Reza Hospital; affiliated to Kermanshah University of Medical Sciences, Iran were included in this study. The informed consent obtained from all the patients. Kermanshah University of Medical Sciences approved the protocol of the study. The patients were included based on the following inclusion and exclusion criteria.

### 2.1. Inclusion criteria

1. Diagnosis of multiple sclerosis according to 2005 McDonald's criteria [9]. 2) History of paresthesia (defined as an abnormal sense of itching, prickling, tingling, burning and numbness in the limbs) or other parts of the body for at least 3 months. 3) Patients who had a numerical rating scale score of 4 or more. The NRS is a self-report estimate of paresthesia intensity measured on an 11-point Likert scale (0 = absent, 1–3 = mild, 4–6 = moderate, 7–10 severe) [10].

### 2.2. Exclusion criteria

1) Pregnancy, lactation or inability to use contraceptives throughout the study regarding females in childbearing ages. 2) Suffering from ischemic pain and other types of pain unrelated

**Table 2**  
Mean scores of numerical rating scale in follow up period.

	Mean score of NRS			P-value
	baseline	30th day	60th day	
Magnet	5/63 $\pm$ 1/96	4/97 $\pm$ 1/96	4/37 $\pm$ 2/03	0.001
placebo	5/45 $\pm$ 1/31	4/75 $\pm$ 1/55	4/3 $\pm$ 1/86	0.003

to multiple sclerosis such as phantom pain due to amputation, arthritis, peripheral neuropathy or cervical radiculopathy. 3) No MS exacerbations (defined as episodes of focal neurological disturbance lasting more than 24 h, without an alternate explanation, and with a preceding period of clinical stability lasting at least 30 days [11]) for one month prior to the study. 4) patients who have pacemaker or other metallic internal devices.

## 3. Procedure

By a computer generated randomization schedule, included patients were randomized as follows: the first group was exposed to a magnetic pulsing field of 4 mT intensity and 15-Hz frequency sinusoidal wave for 20 min per session 2 times per week over a period of 2 months involving 16 sessions. And the second group was exposed to a magnetically inactive field (placebo) for 20 min per session 2 times per week over a period of 2 months involving 16 sessions. Subjects were exposed to a pulsing magnetic field produced by the MAGNETOMED 7200 (medical Italia). This device includes a couch in aluminium with 2 highly sliding tracks and 2 cylinders with 60 cm diameter and 30 cm large for total body treatment, covered with imitation leather. Investigators and patients were blind to the treatments. Both group (active, non-active) did not any specific sensations when the device was on or off. A person who turned off or on the device was differ from investigator performed Follow-up visits and data collection and analysis. Patients allowed to remain on their current regimens but could not add any analgesics or treatments. The outcome was subjective paresthesia as assessed by the NRS [7], were rated daily by patients. Patients' daily ratings of paresthesia were registered by researcher for calculation of mean scores at the beginning of the trial and at 30, 60 days during the trial. The study primary end point was NRS change between baseline and 60 days. The secondary outcome was NRS change between baseline and 30 days. The incidence and severity of adverse events were tabulated throughout the study.

## 4. Statistical analysis

Patient's demographic and clinical information were recorded in a predesigned checklist. The data was analyzed with Statistical Package for the Social Sciences (SPSS) software version 19. Demographic variables and efficacy parameters of two groups were compared. Descriptive statistics were used to report variables of each medication group and also for total participants. Chi square test was employed to test the association of study characteristics between the two groups for categorical variable. Means were compared by the Student's *t*-test. Comparison for paresthesia score on NRS across time in both groups was carried out using Paired *t*-test. Results were reported as mean  $\pm$  standard deviation (SD) and statistical significance was recognized at *p* values < 0.05.

## 5. Result

A total of 63 patients with MS were randomized. Three subjects dropped out of the study.

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