

# The study of NUGA MRT-II relief for low back muscular pain

<b>Submission date</b> 07/04/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 10/06/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 10/06/2011	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N2010-02

## Study information

**Scientific Title**

The study of NUGA MRT-II relief for low back muscular pain: a randomised, patient-assessor, blind, two arm sham device controlled pilot trial

### **Study objectives**

This study aims to explore the pain relieving efficacy of NUGA MRT-II (pulsed electromagnetic fields) for low back muscular pain as a pilot study

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Sang-ji University Oriental Medical Centre Ethics Committee approved on 2nd September 2010

### **Study design**

Randomised patient-assessor blind two arm sham device controlled unicentre pilot trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

### **Participant information sheet**

Not available in web format, please use contact details below to request a patient information sheet

### **Health condition(s) or problem(s) studied**

Low back muscular pain

### **Interventions**

Treatment group : Treated with real equipment for 3 times a week. It takes 10 minutes for each treatment. No other treatments will be applied during this trial.

Treating point : Choose lumbar acupoints (among BL23, BL24, BL25, GV3, GV4, GV5 etc.) mostly on the meridians of governor vessel and bladder meridian, where patients complain pain.

Control group : Treated with false equipment for 3 times a week. It takes 10 minutes for each treatment. No other treatments will be applied during this trial.

Treating point : Choose lumbar acupoints (among BL23, BL24, BL25, GV3, GV4, GV5 etc.) mostly on the meridians of governor vessel and bladder meridian, where patients complain pain.

### **Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Visual analogue scale (VAS) for bothersomeness : measured at baseline, every visit during 2 weeks and after 3 weeks

**Secondary outcome measures**

1. The Korean version of the Roland-Morris disability questionnaire
2. VAS for pain intensity
3. The Korean version of Oswestry Disability Index (ODI)
4. The Korean version of EuroQol 5-Dimension (EQ-5D)
5. The Korean version of SF-36 for quality of life
6. The Korean version of Beck's depression inventory (BDI)
7. Medication use

Measured at baseline, every visit during 2 weeks and after 3 weeks

**Overall study start date**

03/09/2010

**Completion date**

02/09/2011

**Eligibility****Key inclusion criteria**

1. Genders Eligible for Study : Both
2. Patients who have been undergo chronic low back pain for chief complain over 3 months
3. Patient whose age is from 18 to 65
4. Patients whose neurology examination is normal
5. Patients whose bothersomeness for the last week before the participation of the treatment is over Visual Analogue Scale (VAS) 5
6. Patients who are diagnosed as nonspecific low back pain

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

38

**Key exclusion criteria**

1. Patients who have radicular pain
2. Patients who are diagnosed with specific disease which cause low back pain such as metastatic cancer, vertebral fracture, spinal infection, inflammatory spondylitis
3. Patients who are diagnosed with other chronic disease which could affect the result such as cardiovascular disease, diabetic neuropathy, active hepatitis, fibromyalgia, rheumatic arthritis, dementia, haemorrhagic disease, epilepsy
4. Patients who have had or would have spinal surgery
5. Patients who have other skeletomuscular pain as chief complain
6. Patients who have undergone acupuncture treatment for low back pain in last one month
7. Patients who are taking corticosteroids, narcotics, muscle relaxant, anticoagulant drug, herbal medicine for low back pain or other non-propal drugs

**Date of first enrolment**

03/09/2010

**Date of final enrolment**

02/09/2011

## **Locations**

**Countries of recruitment**

Korea, South

**Study participating centre**

283 Woo-San Dong

Wonju

Korea, South

220-717

## **Sponsor information**

**Organisation**

NUGA Medical Co. Ltd (South Korea)

**Sponsor details**

Nuga Best

c/o Lee, Jong Soo

Building 115-5 Samseong-dong

Gangnam-gu

Seoul

Korea, South

135-090

**Sponsor type**

Industry

**Website**

<http://www.nugamedical.com/>

**ROR**

<https://ror.org/02h420k27>

**Funder(s)****Funder type**

Industry

**Funder Name**

NUGA Medical Co. Ltd (South Korea)

**Results and Publications****Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration