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

Submission date	Recruitment status	[ ] Prospectively registered
07/04/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/06/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
10/06/2011	Musculoskeletal Diseases	[ ] 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

Protocol serial number
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

Primary study design
Interventional

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

Study type(s)
Treatment

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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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, fibromyalagia, 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)

ROR
https://ror.org/02h420k27

Funder(s)

Funder type
Industry

Funder Name
NUGA Medical Co. Ltd (South Korea)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration