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Effectiveness evaluation of automatic thermomechanic massage system (SMATH System) in subacute and chronic low back pain treatment

Submission date
14/02/2011

Recruitment status
No longer recruiting

Registration date
14/03/2011

Overall study status
Completed

Last Edited
18/12/2020

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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
RCTSMATH1

Study information

Scientific Title

Effectiveness evaluation of automatic thermomechanic massage system (SMATH System) in subacute and chronic low back pain treatment: a mono-centre double-blind randomised controlled trial

Acronym
RCTSMATH1

Study objectives
Low back pain (LBP) affects more than 85% of adult population at least one time during the life. Health and social costs for LBP are increasing rapidly. Actually there is a general insufficient clinical evidence for endorsed treatments. Massage alone is unlikely to be effective while multidisciplinary methods seem to be the most promising approach.

This clinical study will investigate the effectiveness of new therapeutic medical device (SMATH System) in patients with subacute and chronic LBP. This device associates at the same time the mechanic, thermal and infrared energy released on the patient during automatic and perfectly reproducible treatment cycles. The study will compare results of SMATH treatments versus sham version of the same device which is a similar device able to reproduce on the patient the same sensations of the active SMATH System (vibration, pressure and warmth) but without active principles.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cremona Hospital (Public Hospital Italy) Ethical Committee approved on 29/11/2010 ref:116 /2010 LB

Primary study design
Interventional

Study design
Mono-centre double-blind randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Low Back Pain

Interventions
Automatic thermomechanic massage
SMATH System is a new automatic treatment device for subacute and chronic low back pain.

The treatment arm of the clinical study, plans to treat patients for four weeks with total 14 treatment sessions 45 minutes each. Four sessions will be done during the first and the second week, three treatment sessions will be done during the third and the fourth week.
During these sessions, patient will be treated by the machine with controlled and modulated release of mechanical, thermal and infrared energy. Medical Device simulates a real

multidisciplinary treatment for low back pain because it is capable to assocciate at the same time automatically and with the maximum reproducibility the benefits of massage, moxibustion, thermal therapy, infrared, acupressure, bioresonance.

SMATH is full programmable in function of the spine region we'd like to treat (global spine, cervical area , lumbar area). The clinical study plans to treat patients with the following programs:

week 1 Session 1 Global spine treatment
Session 2 Lumbar treatment
Session 3 Lumbar treatment
Session 4 Global spine treatment

week 2 Same as week 1

week 3 Session 1 Global spine treatment
Session 2 and 3 Lumbar treatment

week 4 Same as week 3

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
SMATH therapy effectiveness evaluation versus sham therapy meausered by RMDQ questionnaire

Key secondary outcome(s)
1. SMATH therapy effectiveness evaluation comparing RMDQ scores at T1 and QRMD at T4.
2. Pain feeling evaluation by visual analogue scale (VAS) questionnaires scores between T1 and T4.
3. Quality of Life evaluation by EQ-5D questionnaires between T1 and T4
4. Verify feasabilty of this RCT in terms of methodology, sample size, drop-out index, etc. in order to be a Pilot Study in the future clinical trials planning in conformity at the evidence based medecine needs

Completion date
06/01/2012

Eligibility

Key inclusion criteria
1. Subjects with subacute and chronic low back pain-diagnosis in conformity with general scientific accepted criteria
2. Subjects age between 18 and 65 years
3. Subjects who sign informed consent
4. Subjects availability to fill questionnaires and to complete the study
5. Roland Morris Disability Questionnaire (RMDQ) score more or equal to 4 at trial (T1)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Pregnancy
2. Subject submitted at physical therapy during 15 days before T1.
3. Subjects submitted at pharmacological cortisone therapy during one month before T1, in this case a 30 days wash-out period will be requested
4. Subjects with active implantable devices
5. Subjects with infusion pumps
6. Subject with spine stabilisation device
7. Subjects with serious osteoporosis
8. Patients with soft or/and bone tissues acute infections
9. Subjects with acute cardiovascular deseases
10. Subjects with neoplastic deseases
11. Subjects with deep vein thrombosis during two months before T1
12. Subjects with rachis traumatic episodes during 3 months before T1

Date of first enrolment
03/01/2011

Date of final enrolment
06/01/2012

Locations

Countries of recruitment
Italy

Study participating centre
Isituti Ospitalieri di Cremona Viale della Concordia, 1
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Sponsor information

Organisation
Physiotherapy and Specialised Rehabilitation Department of Cremona Hospital (Italy)

ROR
https://ror.org/05w07vs91

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Cremona Hospital (Italy)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	study protocol	04/10/2011		Yes	No