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Join the Revolution MTS (Medical Therapy System)

Submission date
08/04/2018

Recruitment status
No longer recruiting

Registration date
17/04/2018

Overall study status
Completed

Last Edited
24/04/2019

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Electrotherapy is the use of electric currents passing through the body to stimulate nerves and muscles for medical treatment. Medical Therapy Systems (MTS) is a new concept in medical electro-therapy that combines six scientifically proven technologies within one portable machine. The use of this can provide immediate pain relief in damaged tissues and stimulate the cells for faster and safer healing. This technology can be applied on all parts of the muscles and skeleton, with minimal discomfort and almost instant results.MTS treatment has been used as a treatment technique since the 1950's and it remains a popular treatment for a range of clinical problems.
This study aims to assess the safety and effectiveness of MTS in this series of musculoskeletal conditions.

Who can participate?
Adults aged 18 to 80 years old with neuro- and musculoskeletal pain (chronic or acute)

What does the study involve?
The participants attend their physiotherapy clinic and receive standard electrotherapy treatment on MTS as per their condition and disease behaviour, according to the iMed MTS protocol. This may be 4 – 12 sessions, given every other day. Participants have demographic data collected, and have pain assessed before and after treatment using a visual scale.

What are the possible benefits and risks of participating?
Participants may benefit from reduced clinic time, as MTS houses six technologies in one system. Therefore the participant does not have to wait to change treatment areas or units, but can continue the full electrotherapy program in one sitting.
All treatments are non-invasive thus there is no risk to patients.

Where is the study run from?
1. Mission Health Multispeciality Physiotherapy Centre (India)
2. University Hospitals of North Midlands NHS Trust (UK)
3. Knowle House Surgery (UK)

When is the study starting and how long is it expected to run for?
March 2017 – October 2018

Who is funding the study?
iMed Group International Ltd (UK)

Who is the main contact?
Dr Gita Patel (Scientific)

Contact information

Type(s)
Scientific

Contact name
Dr Gita Patel

Contact details
51 London End
Beaconsfield
Buckinghamshire
United Kingdom
HP9 2HW

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
07-April 2017

Study information

Scientific Title
Prospective study of Efficacy of Medical Therapy System (MTS)

Acronym
MTS

Study objectives
The study aims to assess the safety and effectiveness of MTS with the application of the following technologies: Low Frequency Ultrasound lower (38 kHz), Micro shockwave emission, Thermal Radiofrequency and Athermal Radiofrequency and Micro Current Emission for pain relief and reduced time to recover

Ethics approval required

Old ethics approval format

Ethics approval(s)
1. Medilink Ethics Committee Gujarat India, 10/04/2017, no reference number
2. HRA, 09/04/2018, ref: 226505 - pending approval

Study design
Multi-centre observational case-control study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Other

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Range of medical conditions including Tendinopathy, Arthropathy, Osteoarthritis (knee) and muscular distractions in both acute and chronic status.

Interventions
The research centre enrolls over 300 patients for a 12 month period and incorporates 6 primary efficacy variables of patients' pain, patients function and physician global evaluation- patients' condition. The results of these variables are aggregated and are presented as the consolidated results of the trial.
28 different pathologies are treated in line with the iMed recommended protocols for dermatome an area of skin that is mainly supplied by a single spinal nerve with Micro Current Emission; angiosome, myotomes and viscera an area of skin and underlying tissues, muscles and abdomen followed with Thermal Radiofrequency and Athermal Radiofrequency (Fraxelling) and Low Frequency Ultrasound and some pathologies with Micro shockwave emission.
Participants receive MTS treatment sessions, delivered at the study visits by the physiotherapist as per pathology and condition of the patient ranging from 4 to 12 sessions, given every other day and global assessment as summarised by the physiotherapist recorded in patient case /medical notes. Demographic data for patients including age, sex, ethnic origin, medical history, pain history medications and physical findings is collected at screening. In addition, annotations are entered by the physiotherapist and recorded for both beginning baseline measurements and after the end of the required number of MTS Sessions (4-8 for acute) and (10-12 for chronic). Regular hospital charts are used as a source document recorded in the investigational site; otherwise study worksheet is created, signed and dated by delegated investigators to work as source document. The investigator clearly marks clinical records to indicate that the subject is enrolled in the MTS procedures.
The participant is followed up by telephone contact to learn if pain has returned 3-6 weeks after

last session of MTS. The participants can return to standard electrotherapy sessions on the other commercial products. Measurements recorded at baseline and after the end of the required number of MTS Sessions (6-8 for acute) and (10-12 for chronic) are collected as VAS scale for pain.
Patients should avoid introductions and changes to other medications and lifestyle choices that could influence end-point variables. These include NSAIDS (Nonsteroidal antiinflammatory drugs) (either topical or oral), AntiTNFalpha Biologics, Opioids, Cannabis and similarities. Introductions and changes are permitted at the discretion of the Investigator.
The treatment is completely non-invasive, fast and effective with no downtime for clients.

Intervention Type
Device

Primary outcome measure
Pain level is measured on the Visual Analogue Scale at baseline and after the end of the required number of MTS Sessions (1 to 3 weeks)

Secondary outcome measures
The exploratory analyses listed below are planned but may not be conducted if deemed to be obsolete during later stages of the trial; other exploratory analyses may be added.
1. Overall efficacy of MTS for tissue rehabilitation is measured using stretching exercises at baseline and 3-9 months
2. Pain relief for both acute and chronic cases is measured using VAS at baseline and 3-9 months
3. Speed of rehabilitation is measured using strengthening exercises at baseline and 3-9 months
4. Quality of Life for chronic sufferers is measured using activities of daily living (ADL) at baseline and 3-9 months
5. Range of motion after injury (acute or chronic) is measured using ergonomic assessment tools at baseline and 3-9 months
6. Safety of the therapy is evaluated by assessing adverse body effects or side effects throughout the study

Overall study start date
01/03/2017

Completion date
31/10/2018

Eligibility

Key inclusion criteria
1. Aged 18 to 80 years
2. Any of the following pathologies: tendinopathy, arthropathy, muscular distractions, osteoarthritis and rheumatoid arthritis
3. Not receiving any other therapy for the duration of clinical program

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
300

Key exclusion criteria
1. Cardiac Pace Makers
2. Defibrillators
3. Primary non treated epilepsy
4. Cemented metal replacement surgery (dental implants acceptable)
5. Non diagnosed pain
6. Not able to communicate sensation of pain to therapist
7. Psychological issues
8. Cancer under active treatment
9. Active Tuberculosis
10. Immunological diseases of skin
11. Lateral arthertrophic sclerosis (ALS)
12. Doubtful medical history
13. Active thrombophlebitis
14. Pregnancy

Date of first enrolment
09/06/2017

Date of final enrolment
31/08/2018

Locations

Countries of recruitment
England

India

United Kingdom

Study participating centre
Mission Health Multispeciality Physiotherapy Centre
4th Floor E-1, Aaron Elegance
Opp. Radhe Bungalows
Bh. Vishwakarma Engineering College
New C.G. Road
Chandkheda

Ahmedabad
India
382424

Study participating centre
University Hospitals of North Midlands NHS Trust
Newcastle Road
Staffordshire
Stoke-on-Trent
United Kingdom
ST4 6QG

Study participating centre
Rame Research
Penntorr Health
Trevol Road
Torpoint
Plymouth
United Kingdom
PL11 2TB

Sponsor information

Organisation
iMed Group International Ltd

Sponsor details
51 London End
Beaconsfield
Buckinghamshire
United Kingdom
HP9 2HW

Sponsor type
Industry

Website
http://www.imedgroup.co.uk/

Funder(s)

Funder type
Industry

Funder Name
iMed Group International Ltd

Results and Publications

Publication and dissemination plan
Intended submission to Physio Therapy Journal in mid-August 2018 as soon as the study is finished and aim to present results to physiotherapists with no downtime for clients.

Intention to publish date
30/08/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Gita Patel.

IPD sharing plan summary
Available on request