# Join the Revolution MTS (Medical Therapy System)

Submission date	Recruitment status	Prospectively registered
08/04/2018	No longer recruiting	∐ Protocol
Registration date	Overall study status	Statistical analysis plan
17/04/2018	Completed	Results
Last Edited	<b>Condition category</b> Musculoskeletal Diseases	Individual participant data
24/04/2019		<ul><li>Record updated in last year</li></ul>

#### 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

#### Protocol serial number

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

## Study type(s)

Other

#### 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(s)

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)

#### Key secondary outcome(s))

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

#### 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

#### Healthy volunteers allowed

No

#### Age group

Adult

### Lower age limit

18 years

#### Sex

All

#### 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

United Kingdom

England

India

## 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

# Funder(s)

## Funder type

Industry

#### **Funder Name**

iMed Group International Ltd

## **Results and Publications**

#### 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

## **Study outputs**

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet 11/11/2025 No Yes