

Can a device that stimulates cell activity using radio electric emissions improve recovery from traumatic joint injuries?

Submission date 20/09/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 30/09/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 07/09/2020	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

It is thought that that physical injury can lead to changes that the injured person is not aware of, which involve psychological and emotional responses, and result in changes to how the person moves the affected limb. This can slow rehabilitation and prevent complete recovery from the injury.

It is possible that radio and electric stimulation of the nerves and tissues could help to reduce recovery time. This study aims to investigate this.

Who can participate?

Adults aged 18-70 years with an injury to the medial collateral ligament (MCL) of the knee that has been diagnosed no more than 4 days previously

What does the study involve?

The radio and electrical stimulation is delivered using the REAC device. On the first treatment day, the device was applied to the ear. Over the next 2 weeks, the participants received 18 treatments with the device probe applied to the injured area. Participants were assessed before the first treatment, after the last treatment and at 30 days after the last treatment. They agreed not to use any other treatment for their knee injury, including medicines and physiotherapy, during the study or to consult the researchers before using any other treatment.

What are the possible benefits and risks of participating?

Participants might benefit from REAC treatments in reduced pain reduction and healing time, without using drugs. REAC treatments have not previously shown any risk or adverse side effects. The study supervisor will monitor the participants and assess the situation if any physical or psychological harm occurs.

Where is the study run from?

The Federal University of Amapá (Brazil)

When is the study starting and how long is it expected to run for?
November 2018 to July 2019

Who is funding the study?
There was no additional funding required. The Rinaldi Fontani Institute & Foundation (Italy) provided the REAC devices.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

UNIFAP-IRF-02-19

Study information

Scientific Title

Neurobiological modulation using the Radio Electric Asymmetric Conveyer (REAC) to improve recovery in acute post-trauma joint injuries

Acronym

REACTJIR

Study objectives

Physical traumas can lead to unconscious neuropsychic alterations which can compromise the rehabilitation result and complete functional recovery. Radioelectric asymmetric conveyer (REAC) neurobiological treatments Neuro Postural Optimization (NPO) and Tissue Optimization (TO) are able respectively to improve neuropsychomotor strategies and the neuropsychophysical response to trauma, and facilitate the recovery process in damaged tissues. The combined use of REAC NPO and TO can envisage a new rehabilitative approach, which aims not only at recovering the outcomes of the physical trauma but also at improving the neuropsychic state that can condition complete recovery.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 02/04/2019, Ethics Committee of the Federal University of Amapá (Rodovia Juscelino Kubitschek de Oliveira, Macapá, Brasil; +55 96 4009-2805; cep@unifap.br), ref: 3.238.424

Study design

Non-randomised non-masked non-controlled study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Post-traumatic knee medial collateral ligament lesion

Interventions

50 outpatients with acute post-traumatic knee medial collateral ligament lesion in care at Health Sciences Department of the Federal University of Amapá, Macapá – Brazil were enrolled for this single-centre study, without randomization, masking, control, and assignment.

The REAC technology device used in this clinical investigation was a model BENE 110 (ASMED, Florence, Italy). The study was conducted administering 2 treatments with the REAC device: the

Neuro Postural Optimization (NPO) and the Tissue Optimization (TO).

Within 4 days after the trauma, 50 subjects were enrolled, but only 45 subjects completed the study. These 45 subjects (23 with grade 3 Medial Collateral Lesion and 22 with grade 2 MCL lesion) were clinically evaluated (T0), both through the medical and the subjective assessments, about pain, swelling, functional impotence, feeling of knee instability, instability to monopodal load and functional dysmetria. Clinical evaluation was repeated after the REAC NPO treatment (T1) and at the end of 18 REAC TO treatments (T2) and at the 30 days follow-up (T3). The NPO consists of a single treatment of few milliseconds administered on a specific area of the auricle pavilion, while the TO treatment is administered by applying the device's asymmetric conveyer probe (ACP), to the area to be treated. The duration of the TO treatment is some minutes. The administration of the 18 TO treatments was carried out over the two-week maximum from the traumatic event.

Intervention Type

Device

Phase

Not Applicable

Primary outcome(s)

Time to healing, with healing assessed using the following assessments by the medical practitioner and subjective assessments of the patient at the first clinical examination, within 4 days after the trauma/accident (T0); immediately after the administration of the Neuro Postural Optimization (NPO) treatment, which is the one-session treatment delivered on the subject's ear (T1); at the end of the 18th session of Tissue Optimization (TO) treatment (T2); at the 30 day-follow up (T3):

Medical assessments:

1. Functional dysmetria. The evaluation of dysmetria is an evaluation of neurological semiology aimed at observing the presence of a dysfunction. Evaluation of dysmetria in the lower limbs can be evidenced, by lightly and symmetrically placing the operator's hands on the femoral quadriceps of the subject being examined in supine position, taking care that the nails of the two left and right thumbs are perfectly aligned. Asking the subject to move from the supine to the sitting position, a progressive misalignment of the two thumbs is highlighted. This manoeuvre allows the operator to perceive and highlight the asymmetric activation of symmetrical muscle groups (dysmetria), such as the quadriceps muscles. In this study, we observed the presence or absence of the phenomenon before (T0) and after NPO treatment (T1).
2. Joint swelling assessment using the scale none (1), little (2), very (3), very much (4)
3. Perception of pain caused during orthopaedic assessment manoeuvres assessed using the scale none (1), little (2), very (3), very much (4)
4. Assessment of patellar ballottement. The procedure to assess patellar ballottement requires that the patient be placed in the supine position with leg straight. The examiner applies anterior to posterior pressure over the patella, and gently oscillates the patella, palpating for motion. Increased motion or spongy joint feel means intra-articular knee swelling. The scale none (1), little (2), very (3), very much (4), was used to assess the patellar ballottement.
5. Valgus Stress Test. There are two versions of this test, valgus at 0 degrees and valgus at 30 degrees. When tested at 0 degrees, the MCL, medial joint capsule, and anterior and posterior cruciate ligaments are stressed. When tested at 30 degrees, the MCL is the primary stabilizer. A positive test occurs when pain or gapping is produced. The following scale was used to assess the increased motion: none (1) = level 1: 0-5 mm of joint opening, no instability; little (2) = level 2: 5-10 mm of joint opening, mild instability; very (3) = level 3: 10-15 mm of joint opening, moderate instability; very much (4) = level 4, >15 mm of joint opening, severe instability.

6. Knee flexion angle measured in degrees with Ortho physical lite, a knee goniometer app installed in an Apple iPhone 6s

Patient's subjective assessments assessed using a questionnaire with items scored using the scale none (1), little (2), very (3), very much (4):

7. Functional impotence

8. Pain

9. Feeling of stiffness

10. Feeling of knee instability

11. Instability to monopodal load

Key secondary outcome(s)

Pain reduction in post-traumatic second and third-degree lesions of the medial collateral ligament of the knee evaluated with verbal analogue scale none (1), little (2), very (3), very much (4) at the first clinical examination, within 4 days after the trauma/accident (T0); immediately after the administration of the Neuro Postural Optimization (NPO) treatment, which is the one-session treatment delivered on the subject's ear (T1); at the end of the 18th session of Tissue Optimization (TO) treatment (T2) and at the 30 day-follow up (T3)

Completion date

30/07/2019

Eligibility

Key inclusion criteria

1. Aged 18-70 years

2. Diagnosed using MRI or ultrasound with a grade 3 or 2 injury to the medial collateral ligament of the knee

3. Diagnosed no more than 4 days before the day of enrolment in the study

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

70 years

Sex

All

Total final enrolment

45

Key exclusion criteria

Previous other joint disorders of the affected knee

Date of first enrolment

29/04/2019

Date of final enrolment

10/05/2019

Locations**Countries of recruitment**

Brazil

Italy

Study participating centre

Universidade Federal do Amapá

Rodovia JK, s/n – Bairro Marco Zero do Equador

Macapá

Brazil

68900-000

Study participating centre

Istituto e Fondazione Rinaldi Fontani

Viale Belfiore 43

Firenze

Italy

50144

Sponsor information**Organisation**

Federal University of Amapá

ROR

<https://ror.org/031va9m79>

Organisation

Rinaldi Fontani Institute and Foundation

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2020	07/09/2020	Yes	No
Participant information sheet	Participant information sheet	26/09/2019	08/10/2019	No	Yes
Participant information sheet		26/09/2019	08/10/2019	No	Yes
Participant information sheet		11/11/2025	11/11/2025	No	Yes