ISRCTN24138677 https://doi.org/10.1186/ISRCTN24138677

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

Registration date
30/09/2019

Overall study status
Completed

Last Edited
07/09/2020

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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?
Dr. Prof. Ana Rita Pinheiro Barcessat, ritabarcessat@gmail.com

Contact information

Type(s)
Scientific

Contact name
Prof Ana Rita Pinheiro Barcessat

ORCID ID
http://orcid.org/0000-0002-5261-6435

Contact details
Universidade Federal do Amapá Rodovia JK, s/n – Bairro Marco Zero do Equador
Macapá
Brazil
68900-000
9681334223
ritabarcessat@gmail.com

Type(s)
Public

Contact name
Prof Ana Rita Pinheiro Barcessat

ORCID ID
http://orcid.org/0000-0002-5261-6435

Contact details
Universidade Federal do Amapá Rodovia JK, s/n – Bairro Marco Zero do Equador
Macapá
Brazil
68900-000
9681334223
ritabarcessat@gmail.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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 conveyor (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 Kubitscheck 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

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

See additional files

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 monopodalic 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 measure
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

Secondary outcome measures
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)

Overall study start date
08/11/2018

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

Age group
Adult

Lower age limit

18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
50

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 Amapà
Rodovia JK, s/n – Bairro Marco Zero do Equador
Macapà
Brazil
68900-000

Study participating centre
Istituto e Fondazione Rinaldi Fontani
Viale Belfiore 43
Firenze
Italy
50144

Sponsor information

Organisation
Federal University of Amapá

Sponsor details
Programa de Pós Graduação em Ciências da Saúde
Universidade Federal do Amapá
Rodovia JK, s/n Bairro Marco Zero do Equador
Macapá
Brazil
68900-000
9681334223
ritabarcessat@gmail.com

Sponsor type
University/education

Website
http://www.unifap.br/

ROR
https://ror.org/031va9m79

Organisation
Rinaldi Fontani Institute and Foundation

Sponsor details
Viale Belfiore 43
Firenze
Italy
50144
055290307
srinaldi@irf.it

Sponsor type
Charity

Website
https://www.irf.it

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
The results of the study might be disseminated through scientific publications, conferences and congresses, seminars and courses.

Intention to publish date
30/06/2020

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?
Participant information sheet		26/09/2019	08/10/2019	No	Yes
Participant information sheet		26/09/2019	08/10/2019	No	Yes
Results article	results	01/07/2020	07/09/2020	Yes	No