

Multicentre, randomised, triple-blind, placebo-controlled study to evaluate the clinical efficacy and safety of an oral rehydration solution (Recuperat-ion®) in the treatment of fibromyalgia

Submission date 13/06/2007	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 26/06/2007	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 02/10/2017	Condition category Musculoskeletal Diseases	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

Hospital Del Mar
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Spain
08003

Additional identifiers

Protocol serial number

RE-FM-01-02

Study information

Scientific Title

Multicentre, randomised, triple-blind, placebo-controlled study to evaluate the clinical efficacy and safety of an oral rehydration solution (Recuperat-ion®) in the treatment of fibromyalgia

Study objectives

Fibromyalgia (FM) is a complex, chronic condition which causes widespread pain and fatigue, as well as a variety of other symptoms that reflect an increased central hypersensitivity to pain and to multiple sensations. Despite the improved knowledge of FM, treatment is still palliative. There is evidence to support the use of antidepressants, cardiovascular exercise, cognitive behavioural therapy, patient education, or a combination of all of them. Complementary therapies are used very often, among them nutritional therapies (vitamins, ions, minerals, and others). Moreover, other treatments with ions and minerals are empirical and remain challenging.

Because there is currently no magic pill for FM, treatment aims at managing FM symptoms to the greatest extent possible. In order to improve their symptoms, especially pain and fatigue, the present study was undertaken to ascertain the influence of an oral beverage solution, Recuperat-ion®; which contains carbohydrates (glucose and fructose), and ions and minerals (sodium, potassium, calcium and magnesium) to improve pain and fatigue in FM patients. Calcium plays a role in mediating muscle contraction and nerve transmission. Magnesium is required for both anaerobic and aerobic energy generation and for glycolysis, either indirectly as a part of the Magnesium-Adenosine Triphosphate (Mg-ATP) complex or directly as an enzyme activator. Sodium aids in nerve impulse conduction and muscle contraction control. In addition to calcium, potassium is important in the regulation of neuromuscular activity.

Ethics approval required

Old ethics approval format

Ethics approval(s)

This study was approved by the ethical committee of each one of the three hospitals:

1. Hospital del Mar: 17th July 2003
2. Hospital General Universitari Vall d'Hebron: 14th May 2003
3. Hospital Clínic i Provincial de Barcelona: 2nd April 2003

Primary study design

Interventional

Study design

Multicentre, randomised, triple-blind, placebo controlled pilot study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Fibromyalgia

Interventions

Group one: Recuperat-ion®

Group two: placebo

A 15-day washout period was required (pre-treatment period). Response to therapy was evaluated at 30, 60, 90, 120, 150, and 180 days (treatment period), and a 30-day observation

period followed (post-treatment period). All patients took four sachets (diluted in 300 ml of water or fruit juice) per day distributed over the four meals. Compliance with trial medication was monitored throughout the study. Laboratory tests were performed at baseline and at 90 and 180 days.

The following was evaluated at the initial visit and at 30, 60, 90, 120, 150, and 180 days:

1. Severity of pain and fatigue (visual analogue pain rating scale)
2. Pain in tender points (digital palpation)
3. General health status and quality of life (Nottingham Health Profile)
4. Psychological well-being (Faces Scale, Hospital Anxiety and Depression Scale)

A global assessment of treatment efficacy was made by the physician and the patient at the end of the treatment period. Comparisons between the two treatments were performed using intention-to-treat-and-cure statistical methods. All statistical procedures were conducted using SPSS statistical software v10.1. This study was approved by the ethics committees of the three hospitals. All patients gave their written informed consent.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Recuperat-ion® (oral rehydration solution)

Primary outcome(s)

To ascertain the influence of an oral beverage solution (Recuperat-ion®) on pain, fatigue and mood in FM patients, measured at initial visit and at 30, 60, 90, 120, 150, and 180 days.

Key secondary outcome(s)

To evaluate:

1. General health status and quality of life (The Nottingham Health Profile), measured at initial visit and at 30, 60, 90, 120, 150, and 180 days
2. Psychological well-being (The Faces Scale, Hospital Anxiety and Depression Scale), measured at initial visit and at 30, 60, 90, 120, 150, and 180 days

Completion date

04/09/2006

Eligibility

Key inclusion criteria

1. Male and female patients between 18 and 65 years old
2. Has FM according to official diagnostic criteria for FM established in 1990 by the American College of Rheumatology (ACR)
3. Duration of the illness of ten years or less

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. History of renal failure (creatinine equal to or superior than 1.8 mL/dL), coronary disease in the last six months, angina, congestive heart disease, diabetes mellitus type one and two
2. Any life-threatening chronic disease (i.e., cancer disease, inflammatory bowel disease and active immune disorders)
3. Rheumatic disease (i.e., inflammatory arthritis, polymyositis, polymyalgia rheumatica)
4. Osteomalacia and osteoporosis
5. Metabolic and endocrine disease (i.e., hypothyroidism and hyperthyroidism, hyperparathyroidism, adrenal insufficiency, metabolic myopathy)
6. Infectious diseases (i.e., Epstein-Barr virus disease, brucellosis)
7. Rheumatic disease of soft tissue and myofascial pain syndrome
8. Parkinsons disease
9. Women to become pregnant or nursing
10. Patients who are enrolled in other clinical trial or patients who participated in other clinical trial in the last 30 days
11. Any psychological or psychiatric disease to compromise the understanding of the instructions giving by the investigator
12. Any subject to be unable to follow a good complementation of the treatment
13. Any patient who denies to give the informed consent to participate in this trial

Date of first enrolment

07/01/2003

Date of final enrolment

04/09/2006

Locations**Countries of recruitment**

Spain

Study participating centre

Hospital Del Mar

Barcelona

Spain

08003

Sponsor information

Organisation

Recuperat-ion Electrolitos, S.L. (Spain)

ROR

<https://ror.org/05pe6et34>

Funder(s)

Funder type

Industry

Funder Name

Recuperat-ion Electrolitos, S.L. (Spain)

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?
Poster results				No	No