ISRCTN91866393 https://doi.org/10.1186/ISRCTN91866393

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 [ ] Statistical analysis plan [X] Results [ ] Individual participant data
Registration date 26/06/2007	**Overall study status** Completed	
Last Edited 02/10/2017	**Condition category** Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 no 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 dHebron: 14th May 2003
3. Hospital Clínic i Provincial de Barcelona: 2nd April 2003

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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.

Secondary outcome measures
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

Overall study start date
07/01/2003

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
A total of 72 patients were enrolled and evaluated and included in the analysis of efficacy and safety

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)

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Sponsor type
Industry

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Funder(s)

Funder type
Industry

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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