Efficacy and safety of eslicarbazepine acetate as therapy in patients with fibromyalgia: a double-blind, randomized, placebo-controlled, parallel-group, multicentre clinical trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	-

Summary

ID

NL-OMON24699

Source
Nationaal Trial Register

Health condition

Fibromyalgia

Sponsors and support

Primary sponsor: BIAL - Portela & Ca, S.A.
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Intervention

Outcome measures

Primary outcome

The primary objective of this study is to assess the efficacy of ESL as therapy in patients with FMS.

The primary efficacy variable will be the change from baseline (the mean of the last 4 patient diary pain assessment scores) to endpoint (mean over the last 4 diary pain intensity scale assessments from the last 7 days before V6) in mean pain.

Secondary outcome

The secondary objective of this study is to assess the safety and tolerability of ESL in patients with FMS.

There will be two key secondary efficacy variables: 30% responder rate at endpoint and the 30% weekly responder rate.
Other secondary efficacy variables based on the pain scores will be 50% responder rates and mean pain intensity per week.
Further secondary efficacy variables will be: Fibromyalgia as assessed by the Fibromyalgia Impact Questionnaire, Patient Global Impression of Change (PGIC), Clinician Global Impression of Change (CGIC), depression as assessed by the
Montgomery Åsberg Depression Rating Scale (MADRS), tender point count, sleep interference as assessed by the Medical Outcome Study (MOS) Sleep Scale, quality of life as assessed by the SF-36 Health Survey, and intake of rescue medication.

Study description

Background summary

Recruiting countries: Austria, Bulgaria, Czech Republic, France, Germany, Hungary, Italy, Poland, Portugal, Netherlands, Romania, Serbia, Slovakia, Spain, United Kingdom and Ukraine.

Study objective

N/A

Study design

The primary efficacy variable will be the change from baseline to endpoint in mean pain.

Intervention

Patients will be treated with either ESL (400 mg QD, 800 mg QD or 1200 mg QD) or placebo for a period of up to 13 weeks.

Contacts

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Eligibility criteria

Inclusion criteria

Main Inclusion Criteria at V1:

1. Patient is male or female, aged 18 or older;

2. Patient meets the ACR 1990 diagnostic criteria for FMS (widespread pain for at least 3 months and pain in at least 11 of 18 tender points);

3. Patient use of allowable nonpharmacological therapies must have been stable for at least 4 weeks prior to V1 (Screening Visit) and must be maintained at the stable regimen throughout the study.

Exclusion criteria

Main Exclusion Criteria:

1. Patient has any of the following: an inflammatory muscle or rheumatologic disease other than FMS; multiple sclerosis; active infections; untreated endocrine disorders; uncontrolled hypo or hyper thyroidism of any type;

2. Patients whose pain is not due primarily to FMS;

3. Patient underwent tender point injection within 30 days before V1 (Screening Visit) and/or patient is unwilling to refrain from tender point injection throughout the study;

4. Patient has abnormal values for antinuclear antibody (ANA > 1/160) or rheumatoid factor (RF > 15 IU/mL) at V1 (Screening Visit);

5. Patient has abnormal Westergren erythrocyte sedimentation rate (ESR) at V1 (Screening Visit) (ESR > 40 mm/h);

6. Patient has creatinine clearance lower than 60 mL/min at Screening;

7. Patient has a Montgomery Åsberg Depression Rating Scale (MADRS) total score ≥ 35 or a score of 4 to 6 on question 10 of the MADRS at V1 (Screening Visit);

8. Patient used prohibited concomitant medications during the 2 week Baseline Period or used fluoxetine during the 30 days before V1 (Screening Visit);

9. Patient used opiates every day for the 30 days before V1 (Screening Visit) for the control of pain related to FMS.

Study design

Design

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-04-2009
Enrollment:	480
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-01-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2050
NTR-old	NTR2167
Other	BIAL-Portela & Ca, S.A. : BIA-2093-210
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A