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

Gepubliceerd: 11-01-2010 Laatst bijgewerkt: 18-08-2022

N/A

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	-

Samenvatting

ID

NL-OMON24699

Bron
NTR

Aandoening

Fibromyalgia

Ondersteuning

Primaire sponsor: BIAL - Portela & Ca, S.A.
À Av. da Siderurgia Nacional
4745 457 S. Mamede do Coronado
Portugal
Phone: +351-229866100
Fax: +351-229866192
http://www.bial.com.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

N/A

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

À Av. da Siderurgia Nacional
4745 457 S. Mamede do Coronado
Patricio Soares Silva, da
[default]

Portugal
+351-229866100

Wetenschappelijk

À Av. da Siderurgia Nacional
4745 457 S. Mamede do Coronado
Patricio Soares Silva, da
[default]
Portugal
+351-229866100

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	21-04-2009
Aantal proefpersonen:	480
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	11-01-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A