Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Multi-Centre Randomised Double Blind Placebo Controlled Clinical Trial of the Effect of Neurotec in Fibromyalgia Syndrome

Protocol summary

Summary

The objective of this study is to determine the effect of Neurotec (a herbal drug) on the Fibromyalgia syndrome. 200 patients who meet the ACR (American College of Rheumatology) criteria and have not any other chronic or systematic diseases will be recruited in 11 academic centres in Iran (6 centres in Tehran and centres of Isfahan, Mashhad, Kerman, Ahvaz, and Yazd).The patients will randomized into two groups through a complete block randomization method separately in each centre and recieve Neurotec (120 mg, one capsule) twice a day or placebo. The duration of treatment period will be 8 weeks and the patients will be visited every other week by a rheumatologist during this period. They will also be followed up for another 2 month-period and will be visited every month. Primary outcome measure of this study is pain which will be measured through the number of tender points and sum of the severities of pain on tender points. Other outcome measures are severity of Fibromyalgia which will be measured through Fibromyalgia Impact Questionnaire (FIQ), anxiety, depression, quality of life, sleep, Patient's Global Impression of Change (PGIC), Clinical Global Impression of Change (CGIC) and adverse effects.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138708061411N2**
Registration date: **2009-06-16, 1388/03/26**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2009-06-16, 1388/03/26

Registrant information

Name
Ahmad Reza Jamshidi
Name of organization / entity
Iran Rheumatology Center
Country
Iran (Islamic Republic of)
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+98 21 8800 4136
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jamshida@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Pars Roos Co.

Expected recruitment start date

2008-11-24, 1387/09/04

Expected recruitment end date

2009-05-24, 1388/03/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Multi-Centre Randomised Double Blind Placebo Controlled Clinical Trial of the Effect of Neurotec in Fibromyalgia Syndrome

Public title

Multi-Centre Randomised Double Blind Placebo Controlled Clinical Trial of the Effect of Neurotec in Fibromyalgia Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Diagnosis of Fibromyalgia defined by American college of Rheumatology criteria (History of

widespread pain has been present for at least three months and tenderness on at least 11 out of 18 points) Age more than 18 year Exclusion Criteria: Presence of any other rheumatologic diseases Receiving any investigational drug within 30 days prior to screening Presence of any other systemic or chronic diseases such as: Myopathy, Vasculitis, Peripheral Vascular Diseases, Chronic hepatic or renal diseases, clinically complicating pulmonary, Cardiac, Hematologic, Gastrointestinal, Endocrine disease or Malignancy. Pregnancy or intention of becoming pregnant during the study period (4 months) Inability to give informed consent according to the agreed process Corticosteroid therapy Any drug hypersensitivity Radiotherapy, Chemotherapy or any immuosuppressive drug use Electrolyte imbalance

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Endocrine & Metabolism Research Center, Ethic Committe

Street address
Fifth Floor, Shariati Hospital, North Kargar St., Tehran, Iran

City
Tehran

Postal code
14114

Approval date
empty

Ethics committee reference number
E-0009

Health conditions studied

1

Description of health condition studied
Fibromyalgia Syndrome

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Severity of Pain

Timepoint
Baseline, second, 4th, 6th, 8th, 12th and 16th weeks of the study

Method of measurement
Sum of severities of tenderpoint via an 11-point scale (0-10)

2

Description
Number of tender points

Timepoint
Baseline, second, 4th, 6th, 8th, 12th and 16th weeks of the study

Method of measurement
number of tender points(out of 18 points based on the American College of Rheumatology)

Secondary outcomes

1

Description
Fibromyalgia Severity

Timepoint
Baseline, second, 4th, 6th, 8th, 12th and 16th weeks of the study

Method of measurement
Fibromyalgia Impact Questionnaire (FIQ)

2

Description
Anxiety

Timepoint
Baseline, 4th, 8th, and 16th week

Method of measurement
Cattell Anxiety Scale

3

Description
Depression

Timepoint
Baseline, 4th, 8th, and 16th week

Method of measurement
Beck Depression Inventory

4

Description
Quality of Life
Timepoint
Baseline, 4th, 8th, and 16th week
Method of measurement
SF-12

5

Description
Sleep
Timepoint
Baseline, 4th, 8th, and 16th week
Method of measurement
Separate questions of adequacy and quality of sleep

6

Description
Patient's Global Impression Change (PGIC)
Timepoint
At the end of 8th and 16th week
Method of measurement
10-point Likert scale (very poor to very improved)

7

Description
Clinical Global Impression of Change (CGIC)
Timepoint
At the end of 8th and 16th week
Method of measurement
10-point Likert scale (very poor to very improved)

8

Description
Adverse effects
Timepoint
Baseline, second, 4th, 6th, 8th, 12th and 16th weeks of the study
Method of measurement
Patient's reports and physical examination and lab tests

Intervention groups

1

Description
Neurotec (capsules containing 120 mg of active gradient) twice a day for 8 weeks
Category
empty

2

Description
Placebo (simillar capsule containing inert substance) twice a day
Category
empty

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr Shariati Hospital
Full name of responsible person
Dr Ahmad Reza Jamshidi
Street address
City

2

Recruitment center
Name of recruitment center
Imam-Khomeini Hospital
Full name of responsible person
Dr Abdorrahman Rostamian
Street address
City

3

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
Dr Ahmad Salimzade
Street address
City

4

Recruitment center
Name of recruitment center
Hazrat-e-Rasool Hospital
Full name of responsible person
Dr Forghanizade
Street address
City

5

Recruitment center
Name of recruitment center
Loghman Hospital
Full name of responsible person
Dr Ahmadzade
Street address
City

6

Recruitment center
Name of recruitment center
Baghyatallah Hospital
Full name of responsible person
Dr Bayat
Street address
City

7

Recruitment center
Name of recruitment center
Yazd
Full name of responsible person
Dr Owlia
Street address
City
Yazd

8

Recruitment center
Name of recruitment center
Ahvaz
Full name of responsible person
Dr Mowla
Street address
City

9

Recruitment center
Name of recruitment center
Kerman
Full name of responsible person
Dr Shakibi
Street address
City
Kerman

10

Recruitment center
Name of recruitment center
Isfahan
Full name of responsible person
Dr Karimifar
Street address
City
Isfahan

11

Recruitment center
Name of recruitment center
Mashhad
Full name of responsible person
Dr Jokar
Street address
Mashhad
City

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Pars Roos Company
Full name of responsible person
Dr Kamran Motamedi
Street address
No. 568,13th alley, Hormozan st., Sahrak-e-Ghods, Tehran, Iran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Pars Roos Company
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ahmad Reza Jamshidi
Position
Professor of Rheumatology
Other areas of specialty/work
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Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty