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Early treatment of idiopathic Parkinson's disease with dopaminergic agonist piribedil in monotherapy. A two-year randomised, parallel, placebo-controlled study in idiopathic Parkinsonian de novo patients

Submission date
07/02/2006

Registration date
31/03/2006

Last Edited
18/04/2018

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration and not expected to be available in the future

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
CL3-04200-006

Study information

Scientific Title
Early treatment of idiopathic Parkinson's disease with dopaminergic agonist piribedil in monotherapy. A two-year randomised, parallel, placebo-controlled study in idiopathic Parkinsonian de novo patients

Acronym
REGAIN

Study objectives
To compare the therapeutic effects of piribedil to placebo, on motor symptoms of idiopathic Parkinson's disease (PD) in the early stage of the disease in out-patients naive to L-dopa

Ethics approval required
Old ethics approval format

Ethics approval(s)
First Ethics Committee approval on 27/11/2000 in Argentina

Study design
International multicentre randomised double-blind placebo-controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Parkinson's disease

Interventions
Piribedil versus placebo

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Piribedil

Primary outcome(s)
Occurrence and time to develop dyskinesia or other motor complications

Key secondary outcome(s))
1. UPDRS III
2. UPDRS II

3. Time to therapeutic failure
4. Percentage of patients requiring treatment with L-dopa
5. L-dopa daily dose
6. UPDRS IV
7. Other motor scores
8. Quality of life

Completion date
11/08/2004

Eligibility

Key inclusion criteria
Out-patients between 30 to 77 years old, with stage 1 to 3 (Hoehn and Yahr) and less than six weeks of previous L-dopa treatment, with less than 3 months of previous treatment by a dopaminergic agonist

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients frequently falling according to unified Parkinson's disease rating scale (UPDRS) II and /or III
2. Prior experience of a dopaminergic complication
3. Prior neurosurgery for PD
4. Previous history of freezing
5. Suspected autosomal juvenile Parkinsonism
6. Atypical Parkinsonian symtoms caused by drugs, metabolic disorders or encephalitis
7. History of psychotic symptoms
8. Poor cognitive performance

Date of first enrolment
10/05/2001

Date of final enrolment
11/08/2004

Locations

Countries of recruitment
Argentina

France

India

Mexico

Portugal

South Africa

Spain

Study participating centre
Institut National de la Santé et de la Recherche Médicale (INSERM) U317
Toulouse
France
31073

Sponsor information

Organisation
Institut de Recherches Internationales Servier (France)

ROR
https://ror.org/034e7c066

Funder(s)

Funder type
Industry

Funder Name
Institut de Recherches Internationales Servier (France)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from https://clinicaltrials.servier.com/ if a Marketing Authorisation has been granted after 2014.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results				No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes