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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 |