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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	Recruitment status	[ ] Prospectively registered
07/02/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
31/03/2006	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/04/2018	Nervous System Diseases	

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Occurrence and time to develop dyskinesia or other motor complications

Secondary outcome measures
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

Overall study start date
10/05/2001

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

Age group
Adult

Sex
Both

Target number of participants
400

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)

Sponsor details

50 rue Carnot
Suresnes
France
92284

Sponsor type
Industry

Website
http://www.servier.com/

ROR
https://ror.org/034e7c066

Funder(s)

Funder type
Industry

Funder Name
Institut de Recherches Internationales Servier (France)

Results and Publications

Publication and dissemination plan
Current version as of 28/03/2018:
Summary results are published in https://clinicaltrials.servier.com.
For interventional Phase III studies ending after the 1st January 2014, the results are/will be published in scientific literature.

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 1st January 2014.

Previous version as of 24/01/2018:
Publication plan:
All phases - Interventional studies ending before 01/10/2018: Summary results will be published on https://clinicaltrials.servier.com/ within 12 months after the end of the study.
All phases - Interventional studies ending after 01/10/2018: Summary results and a lay summary will be published on https://clinicaltrials.servier.com/ within 12 months after the end of the study.
Phase 3 only - The results will be published in scientific literature within 18 months after the end of the study.

Intention to publish date

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