

Randomised controlled trial of Withania somnifera root powder in Parkinsons Disease

Submission date 16/02/2010	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 07/06/2010	Overall study status Completed	☐ Protocol
Last Edited 07/06/2010	Condition category Nervous System Diseases	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Randomised placebo-controlled trial of adjuvant therapy with Withania somnifera in Parkinsons Disease

Acronym
WiS-PD

Study objectives

3 grams per day of Withania somnifera root powder, as an adjuvant therapy to standard care, would improve Unified Parkinson's Disease Rating System (UPDRS) score by more than 10 points in patients with Parkinson's disease compared to placebo.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethical Review Committee of Aga Khan University Hospital, Karachi approved on the 28th of August 2009 (ref: 1266/CHS/ERC-09)

Primary study design

Interventional

Study design

Randomised double blind placebo controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Parkinson's disease

Interventions

Withania Somnifera root powder and placebo

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Efficacy, assessed by Modified Unified Parkinson's Disease Rating System (UPDRS) scale at baseline and 4 weeks.

Key secondary outcome(s)

Safety, assessed by Modified UPDRS scale at baseline and 4 weeks.

Completion date

30/06/2010

Eligibility

Key inclusion criteria

1. Patients, of either sex, aged 30-65, with mild to moderate Parkinson's Disease
2. Levodopa-responsive and participants demonstrate some identifiable 'on response' as observed by investigator
3. Participants demonstrate severe motor fluctuations in spite of individually optimized levodopa treatment investigator.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Diagnosis is unclear or a suspicion of other Parkinsonian syndromes. A group of diseases characterised by symptoms (e.g. tremour, rigidity or stiffness, slow movements and difficulty maintaining balance) common in Parkinson's disease like:-

- 1.1. Patients with Parkinsons Plus syndromes
- 1.2. Essential tremors
- 1.3. Dementia with Lewy bodies
- 1.4. Progressive supranuclear palsy
- 1.5. The syndromes of olivopontocerebellar atrophy
- 1.6. Striatonigral degeneration
- 1.7. Shy-Drager

2. Undergone surgery for the treatment of PD

3. Contraindications to levodopa, or a condition which makes the treatment inadvisable

4. People with any neurological deficit that may interfere with the study assessments

5. Any sign of infection any where in the body at the time of assessment

6. Pregnant or lactating

Date of first enrolment

01/04/2010

Date of final enrolment

30/06/2010

Locations**Countries of recruitment**

Pakistan

Study participating centre

A-1 Pakarab Fertilizer Housing Colony

Multan

Pakistan

75600

Sponsor information

Organisation

Higher Education Commission of Pakistan (HEC) (Pakistan)

ROR

<https://ror.org/038y3sz68>

Funder(s)

Funder type

Government

Funder Name

Higher Education Commission of Pakistan (HEC) (Pakistan)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration