

# Randomised controlled trial of Withania somnifera root powder in Parkinsons Disease

<b>Submission date</b> 16/02/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 07/06/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 07/06/2010	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

## 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 Parkinsons 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)

**Study design**

Randomised double blind placebo controlled trial

**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 email [fahad.saleem@aku.edu](mailto:fahad.saleem@aku.edu) to request a patient information sheet.

**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 measure**

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

**Secondary outcome measures**

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

**Overall study start date**

01/04/2010

**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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

30

**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)

**Sponsor details**

c/o Mr. Abid Ali Gohar (Director Research and Development)

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**Sponsor type**

Government

**Website**

<http://www.hec.gov.pk>

**ROR**

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

## Funder(s)

**Funder type**

Government

**Funder Name**

Higher Education Commission of Pakistan (HEC) (Pakistan)

**Results and Publications****Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration