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Randomised controlled trial of Withania somnifera root powder in Parkinsons Disease

Submission date	Recruitment status	[ ] Prospectively registered
16/02/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
07/06/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/06/2010	Nervous System Diseases	[ ] 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 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

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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