Single-centre open label exploratory phase two pilot study of exogenous oral Melatonin for the treatment of nocturia in Parkinson's

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Contact information of lead PI Country

United Kingdom

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Single-centre open label exploratory phase two pilot study of exogenous oral Melatonin for the treatment of nocturia in Parkinson's

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Parkinson's UK

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Keywords

Research Abstract

Parkinson's is the second commonest neurodegenerative condition. Although predominantly a motor disorder, Parkinson's is associated with non-motor symptoms, nocturia being the commonest. The causes for nocturia are poorly understood, but it has a significant impact on sleep and quality of life in patients and also partners/carers. Current treatment options are limited. Nocturia is often associated with other sleep disturbances and recent evidence suggests

that both may be associated with impaired circadian regulation. A novel approach is to target circadian disturbances, and preliminary studies have suggested that melatonin may be useful in managing nocturia. However no trials of melatonin have been carried out for nocturia in Parkinson's.

Objectives: The primary objective of this study is to evaluate the effects of melatonin on nocturiarelated bother. Secondary objectives are to evaluate: 1) night time urinary frequency, 2) volume of urine at night, 3) incontinence and other lower urinary tract symptoms (LUTS), 4) quality of sleep, 5) quality of life, 6) partners/carer sleep, 7) Melatonin safety profile.

Methods: Twenty patients with Parkinson's reporting nocturia will be invited to join this study. After assessments, they will receive prolonged-release melatonin 2mg nightly for 12 weeks. Symptoms will be evaluated using frequency-volume charts and questionnaires assessing LUTS and sleep. Sleep diary will be kept, and a wrist actigraph will assess sleep efficiency. Partner/carer sleep will be evaluated by questionnaire and sleep diary.

Expected outcomes: This preliminary study will help assess whether melatonin benefits nocturia in Parkinson's, and whether it results in improved quality of sleep and life in patients and their partners/carers.

Further information available at:

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