ISRCTN59798735 https://doi.org/10.1186/ISRCTN59798735

Effect of selective COX-2 inhibition on neuroinflammation in Parkinson's disease

Submission date 28/02/2007	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 01/05/2007	**Overall study status** Completed	
Last Edited 05/09/2007	**Condition category** Nervous System Diseases	

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
16901

Study information

Scientific Title

Acronym
COXPKPD (COX-2 inhibition monitored by PK11195 in Parkinson's Disease)

Study objectives
Celecoxib inhibits cerebral activated microglia in Parkinson's disease

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Review Committee of the University Medical Center Groningen. Approval pending as of 28 February 2007.

Study design
Open, non-randomised, non-placebo controlled, pilot phase trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Parkinson's disease

Interventions
Interventions amended as of 05/09/2007:
All participants will receive celecoxib oral medication of 100 mg daily for 1 month.

Interventions provided at time of registration:
Celecoxib oral medication of 100 mg daily for 1 month.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Celecoxib

Primary outcome measure
One baseline and one follow-up Positron Emission Tomography (PET) scan (PK11195) and one Magnetic Resonance Imaging (MRI) scan will be performed to assess the reduction of specific cerebral radiotracer uptake (volume of distribution according to Logan graphical method) after celecoxib.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/04/2007

Completion date
31/12/2007

Eligibility

Key inclusion criteria
1. Early Parkinson's disease patients
2. Hoehn and Yahr Parkinson's Disease Rating Scale (HY) 1 - 2

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
20

Key exclusion criteria
Gastrointestinal diseases

Date of first enrolment
01/04/2007

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
Netherlands

Study participating centre

University Medical Center Groningen (UMCG)
Groningen
Netherlands
9700 RB

Sponsor information

Organisation
University Medical Center Groningen (UMCG) (The Netherlands)

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Medical Center Groningen (UMCG) Neurology department deparmental funding (The Netherlands)

Funder Name
Stichting International Parkinson Fonds (The Netherlands)

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