Biodistribution of [11C]laniquidar in healthy volunteers.

Gepubliceerd: 15-09-2010 Laatst bijgewerkt: 18-08-2022

Whole body radiation of 370MBq [11C]laniquidar is approximately 2mSv.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25649

Bron
NTR

Aandoening

biodistribution, dosimetry, healthy volunteers

Ondersteuning

Primaire sponsor: VU University Medical Center
Overige ondersteuning: EURIPIDES

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Biodistribution and dosimetry of [11C]Laniquidar in healthy volunteers.

Toelichting onderzoek

Achtergrond van het onderzoek

Resistance to current drug therapy is an issue for approximately 30% of all people who develop epilepsy. Consequently, there is a pressing need to develop new and more effective treatments. P-glycoprotein (P-gp) seems to be involved in drug resistance. P-gp is an efflux transporter, which is located at the blood-brain barrier (BBB) and transports substrates (including multiple CNS drugs) from brain to blood and cerebrospinal fluid. Overexpression of P-gp is thought to be an important mechanism of pharmacoresistance in epilepsy. Availability of non-invasive imaging methods that would allow for an assessment of distribution and function of P-gp in the brain is of vital importance. Novel PET probes, designed to specifically measure P-gp expression, need to be developed. Laniquidar is an antagonist of P-gp and therefore it should bind in a dose dependent manner. Recently, this compound was labelled with carbon-11, making it a potential tool for measuring P-gp expression. Initial results of brain uptake of [11C]laniquidar in rats were inconclusive. The rat biodistribution studies in peripheral organs showed the highest uptake in the spleen, heart, kidney and lung. This might be due to the formation of labelled metabolites. Based on these biodistribution studies, the expected dose for a standard 370 Mega Becquerel (MBq) injection would be 1.85mSv (0.005mSv/MBq), well below the accepted safety limit for human studies. Nevertheless, only direct studies in humans can be used to determine the optimal (safe) dose of [11C]laniquidar. One condition for human use is that, in general, an injected dose of around 370 MBq is needed to allow for accurate measurements of plasma and tissue kinetics.

Doel van het onderzoek

Whole body radiation of 370MBq [11C]laniquidar is approximately 2mSv.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

1x[11C]Laniquidar whole-body PET-low-dose CT scan.

A low-dose whole-body CT scan is performed after which a single dose of 370MBq [11C]Laniquidar is venously injected. At the same time a whole-body PET scan is repeated during 1 hour.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age between 18-65 years;

2. Good physical health evaluated by medical history, physical (including neurological) examination and screening laboratory tests;

3. Written informed consent of each subject.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Any clinical significant abnormality of any clinical laboratory test;

2. Any subject who has received any investigational medication within 30 days prior to the start of this study, or who is scheduled to receive an investigational drug;

3. Major psychiatric or neurological disorder;

4. History of alcohol and/or drug abuse (DSM-IV criteria);

5. History of coagulation problems;

6. Any sign of cardiovascular disease;

7. Current use of any medication, other than contraceptive medication;

8. Breast feeding;

9. Pregnancy;

10. Unable to understand or read the Dutch language.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2010
Aantal proefpersonen:	6
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	15-09-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2405
NTR-old	NTR2513
Ander register	METC VUmc : 10186
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A