Een onderzoek naar de opname, verdeling en uitscheiding van bedaquiline, een geneesmiddel tegen tuberculose, in mensen met type II diabetes

Gepubliceerd: 26-02-2018 Laatst bijgewerkt: 18-08-2022

It is well documented that T2DM patients have altered pharmacokinetics due to disease related changes in absorption, distribution and metabolic processes. As such, T2DM may thus affect bedaquiline exposure which may result in reduced efficacy. In…

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26912

Bron
Nationaal Trial Register

Verkorte titel
PANDEMIC

Aandoening

type 2 diabetes mellitus
tuberculosis
bedaquiline
comorbidity
drug resistance

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

A population approach PK model will be developed, describing the plasma bedaquiline concentrations over time. The pharmacokinetic endpoints reported depend on the model structure that describes the data best, but will include model parameters (e.g. volumes of distribution, clearances) and model derived parameters for exposure when appropriate (e.g. the area under the plasma concentration-time curve from zero to infinity, the maximum plasma concentration, time to reach maximum plasma concentration, half-life)

Toelichting onderzoek

Doel van het onderzoek

It is well documented that T2DM patients have altered pharmacokinetics due to disease related changes in absorption, distribution and metabolic processes. As such, T2DM may thus affect bedaquiline exposure which may result in reduced efficacy. In this study we will evaluate, for the first time, the pharmacokinetics of bedaquiline in patients with comorbid T2DM

Onderzoeksopzet

Venous blood samples will be taken at screening and pre-dose (2 samples of 10 mL) and will be assessed for clinical chemistry and laboratory assessment.

Prior to dosing an oral swab will be obtained for genotyping.

Blood samples of 4 mL will be collected at t=0, 1, 2, 3, 4, 5, 6, 8, 10, 24, 48 and 72h after administration of bedaquiline for quantification of total plasma concentration of bedaquiline.

Morning urine voids will be collected on all three study days in order to determine the urinary albumin:creatinine ratio.

Onderzoeksproduct en/of interventie

single dose 200 mg PO bedaquiline

Contactpersonen

Publiek

Dept Clinical Pharmacy and Pharmacology, University Medical Center Groningen
Jasper Stevens
Groningen
The Netherlands
050-361-7875

Wetenschappelijk

Dept Clinical Pharmacy and Pharmacology, University Medical Center Groningen
Jasper Stevens
Groningen
The Netherlands
050-361-7875

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Healthy volunteers must meet all of the following criteria In order to be eligible to participate in this study:

- Between 18 and 50 years of age

- BMI between 18,5 and 30 (Kg/m2)

- Written informed consent

T2DM patients must meet all of the following criteria in order to be eligible to participate in this study:

- Diagnosed with T2DM

- Using metformin with or without an SUD, or solely a SUD.

- Between 18 and 50 years of age

- BMI between 18,5 and 40 (Kg/m2)

- Written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Drug hypersensitivity to bedaquiline.

- History of cardiovascular disease.

- Hypokalemia (<3,5 mmol/L).

- eGFR<30 ml/min.

- Drugs with pro-arrhythmic potential or QT-prolongation.

- Pregnant women, breastfeeding women and women of child-bearing potential who are not using reliable contraception.

- Participation in any clinical investigation within 3 months prior to initial dosing or longer if required by local regulations, and for any other limitation of participation based on local regulations.

- Donation or loss of 400 ml or more of blood within 8 weeks prior to initial dosing

- Any medication, surgical or medical condition which might significantly alter the absorption, distribution, metabolism, or excretion of study medication including, but not limited to any of the following:

- Major gastrointestinal tract surgery such as gastrectomy, gastroenterostomy, or bowel resection

- Gastro-intestinal ulcers and/or gastrointestinal or rectal bleeding within last six months

- Pancreatic injury or pancreatitis within the last six months

- Evidence of hepatic disease as determined by any one of the following: ALT or AST values exceeding 3x ULN at inclusion visit, a history of hepatic encephalopathy, a history of esophageal varices, or a history of portocaval shunt.

- Inducers and inhibitors of the cytochrome P-450 3A4 isoenzyme (CYP3A4)

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2018
Aantal proefpersonen:	36
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL6867
NTR-old	NTR7045
Ander register	201700787 : 2017-004490-14

Resultaten