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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26912

Source
Nationaal Trial Register

Brief title
PANDEMIC

Health condition

type 2 diabetes mellitus
tuberculosis
bedaquiline
comorbidity
drug resistance

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

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)

Secondary outcome

When appropriate, covariates will be identified (e.g. CYP3A4 phenotype or bodyweight) that explain inter-individual variability. Particular focus will lie on identifying the covariates CYP3A4 phenotype, disease status (T2DM vs. healthy controls), HbA1C, UACR and type of medication (e.g. metformin vs. SUD).

Study description

Study objective

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

Study design

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.

Intervention

single dose 200 mg PO bedaquiline

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2018
Enrollment:	36
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6867
NTR-old	NTR7045
Other	201700787 : 2017-004490-14

Study results