Pharmacokinetic modeling of mitotane

Published: 24-05-2012
Last updated: 29-04-2024

The main objective of this study is to construct a population-pharmacokinetic model, in order to evaluate the influence of patient characteristics on the pharmacokinetics of mitotane in patients treated with this oral therapy.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Adrenal gland disorders
Study type	Observational invasive

Summary

ID

NL-OMON37374

Source
ToetsingOnline

Brief title
Pharmacokinetic modeling of mitotane

Condition

- Adrenal gland disorders

Synonym
adrenocortical carcinoma, cancer of the adrenal cortex

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: Eigen middelen

Intervention

Keyword: Mitotane, Modeling, Pharmacokinetics

Outcome measures

Primary outcome

Main study parameters are observed mitotane plasma levels, mitotane doses administered and time between mitotane dosing and sampling.

These parameters combined with patient characteristics will be used in order to construct a population PK-model using specialized software.

Clinical application of these findings may permit selection of an appropriate dosing schedule, in order to more rapidly achieve therapeutic plasma levels.

Secondary outcome

Secondary Objective: Screen for the influence of patient characteristics on pharmacokinetics of mitotane in patients treated with oral therapy.

Study description

Background summary

Very little information is known about the pharmacokinetics of mitotane. Adequate dosing is important, as the drug is only proven to be effective when a plasma level of 14 mg/L is maintained. Current dosing regimes are formulated based on expert opinion. Differences in plasma levels between patients are thus far poorly understood.

Study objective

The main objective of this study is to construct a population-pharmacokinetic model, in order to evaluate the influence of patient characteristics on the pharmacokinetics of mitotane in patients treated with this oral therapy.

Study design

This study was designed as an observational study.

Study burden and risks

Participation in the study requires one hospital visit, time spent at the hospital is approximately 8 hours. Ten plasma samples of 5mL each will be collected, from which one sample will be stored for future use in a pharmacogenetic study. Oral treatment with mitotane will be administered in accordance with patient*s own dosing schedule. Risks associated with participation are related to venapuncture. There will be no individual benefit associated with participation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Treatment with oral mitotane ongoing for > 24 weeks;
- Age > 18 years;
- Able to comply with the protocol;

- Written informed consent;

Exclusion criteria

- Any severe acute or chronic medical or psychiatric condition, or laboratory abnormality that would impart, in the judgment of the investigator, excess risk associated with study participation, or which, in the judgment of the investigator, would make the patient inappropriate for entry into this study.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-06-2012
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	24-05-2012
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	25-09-2012
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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
EudraCT	EUCTR2011-006284-22-NL
CCMO	NL39880.015.12