Evaluation of the intracellular pharmacokinetics of decitabine in patients with leukemia or myelodysplasia

Published: 23-04-2018
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The present study will be focused on exploring the intracellular pharmacokinetics of decitabine

Ethical review	Approved WMO
Status	Will not start
Health condition type	Leukaemias
Study type	Observational invasive

Summary

ID

NL-OMON46533

Source
ToetsingOnline

Brief title
intracellular PK of decitabine in patients with leukemia/myelodysplasia

Condition

- Leukaemias

Synonym
leukemia and myelodysplasia

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: decitabine, intracellular, pharmacokinetics

Outcome measures

Primary outcome

• Intracellular concentrations of decitabine

• Intracellular concentrations of decitabine phosphates

• Amount of genomic DNA incorporated decitabine related to the amount of

incorporated 2*-deoxycytidine (endogenous compound)

• Assessment of the methylation grade of genomic DNA by quantitation of

methylated 2*-deoxycytidine (5-methyl-2*-deoxycytidine)

Secondary outcome

not applicable

Study description

Background summary

A recent publication by Anders et al. describes, for the first time, an analytical method to quantitate genomic DNA incorporated decitabine in a preclinical setting. The new method can be used for the measurement of intracellular decitabine phosphates, as well as genomic DNA incorporated decitabine. This study would be the first to describe the incorporation of decitabine in a clinical setting.

Study objective

The present study will be focused on exploring the intracellular pharmacokinetics of decitabine

Study design

In subjects diagnosed with AML or MDS who are treated with 10-days decitabine, additional whole blood samples will be collected on day 1, day 5 and day 10 of

the same decitabine treatment cycle. Patients will be approached for the first 2 cycles of decitabine.

Study burden and risks

not applicable

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

Diagnosed AML or MDS according to WHO-guidelines, >18 years, planned for treatment start with decitabine (ten-day cycle)

Exclusion criteria

<18 years

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	6
Type:	Anticipated

Ethics review

Approved WMO Date:	23-04-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	13-11-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL63972.042.17