Intracellular drug measurements to predict toxicity in high-dose methotrexate therapy in leukaemia and central nervous system lymphoma.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24644

Source
NTR

Brief title
HAL study

Health condition

leukaemia and central nervous system lymphoma
acute leukemie en centraal zenuwstelsel lymfoom

Sponsors and support

Primary sponsor: Erasmus Medical Center
Source(s) of monetary or material Support: Erasmus Medical Center

Intervention

Outcome measures

Primary outcome

To investigate the pharmacokinetics and determinants of MTX-PG accumulation in plasma, lymphocytes and erythrocytes in
adult CNS lymphoma and leukemia patients treated with HD-MTX

Secondary outcome

To investigate whether intracellular MTX levels are related to toxicity in adult HD-MTX therapy

Study description

Background summary

High-dose Methotrexate (HD-MTX) chemotherapy is the cornerstone of the treatment of central nervous system lymphoma (PCNSL) and acute lymphoblastic leukaemia (ALL) . Although MTX is a relatively safe and effective drug, >35% of patients experience adverse events, which is poorly predicted by the highly variable plasma MTX levels. Intracellular MTX levels have been shown to correlate better with clinical outcome in ALL but are difficult to measure. Recently, we developed an intracellular MTX assay that can be used in routine clinical practice. We hypothesize that intracellular MTX levels predict toxicity in HD-MTX therapy. The aim of this study is to investigate A) cellular MTX pharmacokinetics and its determinants, and B) whether intracellular MTX levels are related to toxicity in adult HD-MTX administration.

Study objective

intracellular MTX levels predict toxicity in HD-MTX therapy

Study design

Pre MTX
72 hours post MTX

Intervention

bloodsampling

Contacts

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Eligibility criteria

Inclusion criteria

- All adult patients treated in the Erasmus MC with HD-MTX for a CNS lymphoma or ALL

- Written informed consent

Exclusion criteria

none

Study design

Design

Study type:	Interventional
Intervention model:	Other

Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2016
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	29-12-2015
Application type:	First submission

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	NL5465
NTR-old	NTR5609
Other	NL54566.078.15 : MEC 2015-659

Study results