The Effect of Prehydration on the Pharmacokinetics of Low-dose Cisplatin

Published: 08-07-2015
Last updated: 19-04-2024

To determine if there is a difference in the pharmacokinetics of low-dose cisplatin with and without prehydration.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON42571

Source
ToetsingOnline

Brief title
Prehydration and low-dose cisplatin

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
cancer, malignancy, Tumor

Research involving
Human

Sponsors and support

Primary sponsor: Nederlands Kanker Instituut
Source(s) of monetary or material Support: NKI-AVL

Intervention

Keyword: Cisplatin, Prehydration

Outcome measures

Primary outcome

The main study parameter is a difference in pharmacokinetics (Cmax and AUC) of cisplatin.

Secondary outcome

The secundary study parameter is a difference in platinum-DNA adducts in white blood cells and a difference in urinal excretion of cisplatin.

Study description

Background summary

Low-dose cisplatin can cause nephrotoxicity, which can be reduced by prehydration. In 2011, the clinical treatment protocol in AVL was altered from optional prehydration in patients with manifest nephrotoxicity, to standard prehydration in all patients. However, pre-clinical data recently demonstrated that prehydration can lower the cisplatin concentration in the tumor. This effect now needs to be evaluated in humans. Since measuring tumoral cisplatin concentrations is difficult in patients, this study will focus on the pharmacokinetics of cisplatin with and without prehydration.

Study objective

To determine if there is a difference in the pharmacokinetics of low-dose cisplatin with and without prehydration.

Study design

A 2x2 cross-over design. Patients in group 1 will receive no prehydration on day 1 and prehydration on day 2. Patients in group 2 will receive prehydration on day 1 but no prehydration on day 2. The pharmacokinetics of cisplatin will be measured in blood samples and the excretion of cisplatin will be measured in urine.

Intervention

Patients in group 1 will receive no prehydration on day 1 and prehydration on day 2. Patients in group 2 will receive prehydration on day 1 but no prehydration on day 2. On all other days (up to 25), pre-hydration will be given according to standard clinical protocol.

Study burden and risks

Burden: Patients will need an extra intravenous catheter twice, through which blood samples will be taken 9x in one day. Patients will need to stay in the hospital for 7 hours on two days instead of the usual 2 hours.

Risks: Removing the prehydration can lead to nephrotoxicity. To keep this risk as low as possible, only patients receiving daily low-dose cisplatin (6 mg/m2) are included and only 1 of the 24 or 25 doses is given without prehydration.

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

- Scheduled for concurrent low-dose cisplatin and radiotherapy
- > 18 years old
- GFR > 60
- able to provide informed consent

Exclusion criteria

- Prior treatment with platinum compounds
- Poor kidney function (GFR <60)

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-01-2019
Enrollment:	40
Type:	Actual

Medical products/devices used

Product type:	Medicine

Brand name:	0.9% NaCl
Generic name:	0.9% NaCl (sodium chloride)
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Cisplatin
Generic name:	Cisplatin
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	08-07-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	10-09-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	21-12-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	EUCTR2015-002026-39-NL
CCMO	NL53446.031.15