Feasibility of the analysis of platinum-DNA adducts in tumour tissue in cisplatin-treated patients with advanced gastric cancer

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The purpose of this study is to determine the feasibility of a sensitive technique for the analysis of platinum-DNA adducts in tumour tissue. We will:-Assess the feasibility of the analysis of platinum-DNA adducts in tissue using inductively coupled...

Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal conditions NEC
Study type	Observational invasive

Summary

ID

NL-OMON30393

Source
ToetsingOnline

Brief title
Platinum-DNA adduct analyisis in tumour tissue

Condition

- Gastrointestinal conditions NEC

Synonym
gastric cancer, gastric malignancies

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis

Source(s) of monetary or material Support: farmacologische research gelden

Intervention

Keyword: Feasibility, gastric cancer, platinum-DNA adducts, tumour tissue

Outcome measures

Primary outcome

-Assessment of the feasibility of the analysis of platinum-DNA adducts in tissue using inductively coupled plasma mass spectrometry and the determination of the minimal amount of tissue needed for the assessment of platinum-DNA adducts

-Determination of platinum-DNA adducts in vital gastric tumour tissue, necrotic gastric tumour tissue and normal gastric tissue 24 hours after start of chemotherapy

-Determination of platinum-DNA adducts in PBMCs at the start of the infusion, 1, 2, 3, 4, 4.5, 5, 6, 8 and 24 hours after start of the infusion

-Determination of platinum in plasma and plasma ultrafiltrate at the start of the infusion, 1, 2, 3, 4, 4.5, 5, 6, 8 and 24 hours after start of the infusion

Secondary outcome

Not applicable.

Study description

Background summary

Cisplatin exerts its cytotoxic action by formation of platinum-DNA adducts. Often, these adducts are quantitated in peripheral white blood cells as surrogate for levels in tumour tissue. Some studies, however, have shown that good correlations between levels in peripheral blood mononuclear cells (PBMCs) and tumour tissue are lacking. Therefore, it is of interest to explore platinum-DNA adduct levels in tumour tissue. For this aim we developed a sensitive technique to determine platinum-DNA adducts in tumour cells implying only a small amount of tumour tissue.

Study objective

The purpose of this study is to determine the feasibility of a sensitive technique for the analysis of platinum-DNA adducts in tumour tissue. We will:

-Assess the feasibility of the analysis of platinum-DNA adducts in tissue using inductively coupled plasma mass spectrometry and determine the minimal amount of tissue needed for isolation of DNA and the analysis of platinum-DNA adducts.

-Determine whether there is a relationship between the amount of platinum-DNA adducts in normal gastric tissue, vital gastric tumour tissue, necrotic gastric tumour tissue and PBMCs.

Study design

This is a prospective study in which patients who receive cisplatin for gastric cancer will be included. Patients will be asked to donate blood samples at predefined time points during and after the first cisplatin chemotherapy infusion. Cisplatin will be administered in a 4-hour during infusion. A gastroscopy, including biopsy will be performed 24 hours after start of the chemotherapy infusion.

Study burden and risks

Blood samples will be taken during and after cisplatin infusion. Therefore patients will be exposed to extra blood sampling. Furthermore, approximately 150 mg tissue of normal gastric tissue, vital tumour tissue and necrotic tumour tissue will be collected during a gastroscopy 24 hours after the start of cisplatin infusion. The inconvenience of this gastroscopy is minimised by throat anaesthesia and sedation. Biopsies taken during gastroscopy can lead to small bleedings. These bleedings, however, generally stop immediately.Patients will not experience benefit of participation in this study. However, data acquired from this study will be used to assess the value of the determination of platinum-DNA adducts in tumour tissue. These data will be used to optimise

the method for the determination of platinum-DNA adducts in tissue.

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

-Patients treated with cisplatin for gastric cancer in The Netherlands Cancer Institute
-Patients who receive the first cisplatin chemotherapy infusion
-Age >= 18 years
-Performance: WHO 0-2
-Life expectancy > 3 months
-Written informed consent prior to participation
-Able and willing to undergo blood sampling for platinum analysis
-Able and willing to undergo tissue biopsy during gastroscopy. The eligibility of patients to undergo gastroscopy and biopsy is left to the discretion of the responsible oncologist

Exclusion criteria

Any psychological, familial, sociological or geographical condition that may interfere with compliance with the study protocol

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2006
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Date:	23-11-2006
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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	NL14956.031.06