Optimization of a standard protocol for linear amplification of tumor RNA extracted from Fine Needle Aspirates (FNA) of pancreatic tumors.

Published: 17-09-2010
Last updated: 30-04-2024

Optimize the protocol for linear amplification of tumour RNA extracted from FNA's under GMP conditions.

Ethical review	Approved WMO
Status	Pending
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational invasive

Summary

ID

NL-OMON34795

Source
ToetsingOnline

Brief title
Optimization of a tumor RNA- amplificationprotocol

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified

Synonym
pancreatic adenocarcinoma, pancreatic cancer

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W,MLDS

Intervention

Keyword: FNA, Linear amplification, pancreatic carcinoma, tumor RNA

Outcome measures

Primary outcome

Determination of the amplified RNA quality by performing a qualitative assay

before and after amplification using Taqman probes.

Secondary outcome

not applicable

Study description

Background summary

Pancreatic cancer (PC) has a very poor prognosis despite conventional treatment. Therefore, development of new strategies to treat this aggressive form of cancer is urgently needed. In the past decades a novel approach has been considered to be applicable to cancer therapy: Immunotherapy using Dendritic Cell (DC) vaccines. A few years ago a new research group has been established at the AMC in collaboration with Sanquin. For the last years this group is occupied with the development of a vaccine where DCs are pulsed with autologous total tumour RNA. In the future, these vaccines will be used to induce a strong Cytotoxic T-cell (CTL) response specifically directed against the patients own tumour cells. In the future phase 1 clinical trial we want to administer a maximum of 10 vaccines. These vaccines mainly consist of autologous patient material and in order to obtain this material (monocytes and cancer cells) patients need to undergo invasive and time consuming procedures such as endoscopies and leukapheresis procedures. In order to subject patients to as less invasive- and time consuming procedures as possible, our aim is to produce multiple vaccines at once. The total tumor RNA is obtained from FNA's of the patient's tumor, but due to limited access to pancreatic tumors, the amount of RNA obtained in this way is only sufficient for the production of a single vaccine. To obtain a sufficient amount of RNA for the production of multiple vaccines, the RNA obtained from FNA*s will be linearly amplified. In this study the protocol for linear amplification of total tumor RNA will be

optimized.

Study objective

Optimize the protocol for linear amplification of tumour RNA extracted from FNA's under GMP conditions.

Study design

It concerns an observational study with PC patients who are primarily being referred to the AMC for staging and treatment. A total of thirty patients will be included at the outpatient clinic after receiving informed consent and signing written informed consent. Patients will undergo a procedure where patient material will be obtained for this study. This procedure will be a routine procedure performed at the AMC, where the patients tumour will be staged and material will be taken for histological diagnosis. During this procedure we will take extra cytologic material that we will use to optimize our protocol for the linear amplification of total tumor RNA.

Study burden and risks

Time: The EUS will be prolonged with a maximum of five minutes due to obtaining extra material for the study. Interventions: During the planned EUS extra FNA's will be obtained. There's a scarce chance of bleeding from the aspiration site after this procedure and there is a very small chance of infection due to the FNA.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

inoperable pancreatic adenocarcinoma

Exclusion criteria

operable PC

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2010
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL30116.018.10