The effect of micellar curcumin (Espera C®) on the molecular immune signature of pancreatic cancer patients.

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To determine whether micellar curcumin is able to restore functional lymphocytes in pancreatic cancer patients with stable disease after standard of care treatment.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Exocrine pancreas conditions
Study type	Interventional

Summary

ID

NL-OMON48475

Source
ToetsingOnline

Brief title
Espera C® monitoring

Condition

- Exocrine pancreas conditions
- Gastrointestinal neoplasms malignant and unspecified

Synonym
pancreatic cancer, pancreatic ductal adenocarcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Espera supplements B.V.

Intervention

Keyword: curcumin, immune function, pancreatic cancer

Outcome measures

Primary outcome

To determine whether micellar curcumin (Espera C®) is able to skew the T-cell subsets of PDAC patients with stable disease after standard of care treatment. Additionally, we will determine whether curcumin*s effects on the immune status is reflected by improvement in the SIII and the differences in immunology-related gene expression and cell types between PDAC patients.

Secondary outcome

To determine whether curcumin*s effects on the immune status is reflected by improvement in the SIII and the differences in immunology-related gene expression and cell types between PDAC patients.

Study description

Background summary

Patients diagnosed with pancreatic cancer have a very poor survival rate. The recognition of cancer inflammation as an important hallmark of cancer, as well as the recognition of the important role of the immune system in cancer surveillance and elimination, has led to the examination of various inflammatory markers as prognostic factors in cancer. Pancreatic cancer is characterised by tumor-mediated immune suppression and an imbalance in immune cells favouring the subsets that are associated to a poor prognosis (high T-regulatory, low cytotoxic lymphocytes). The systemic inflammation immune index (SIII) represents systemic inflammatory responses and can be used to indicated the host inflammatory and immune status in pancreatic cancer patients. Recently, we found that the SIII is an independent predictor of both cancer-specific survival and recurrence in patients with resectable pancreatic ductal adenocarcinoma (PDAC).
The oral food supplement curcumin has been deemed as a potent, pleiotropic

anti-inflammatory drug that can modulate the immune system. In pancreatic cancer patients, curcumin could restore functional lymphocytes (T cell populations) and skew the immune response from an unfavourable to a favourable one.

Study objective

To determine whether micellar curcumin is able to restore functional lymphocytes in pancreatic cancer patients with stable disease after standard of care treatment.

Study design

Single center, prospective, open label study. PDAC patients with stable disease after standard of care treatment will be eligible to participate in this study. Participants currently on over the counter curcumin will be asked to stop treatment for at least 2 weeks in order to wash out any curcumin from their system which could interfere with our measurements. During the study, blood samples will be drawn at 2 sampling points: baseline (after 2 weeks wash out if applicable) and after 6 weeks of Espera C® treatment. Each blood sample consists of 1 x 10 ml EDTA blood and 1 x 3 ml Tempus blood. The Tempus blood will be used to isolate RNA in order to conduct immune profiling using multiplex gene expression with NanoString.

Intervention

Investigational treatment consists of oral micellar curcumin (Espera C®). Patients will receive 2dd2 capsules (18 mg micellar curcumin/capsule) for a period of 6 weeks. Patients will undergo blood sampling at baseline and after 6 weeks of oral micellar curcumin (Espera®).

Study burden and risks

Patients with stable disease will undergo two additional blood sampling moments. The baseline is drawn during a standard of care visit) and the second sample is drawn after 6 weeks of oral micellar curcumin (Espera C®). Curcumin is a safe product with little to no side effects, so the risks associated with participation are limited. In PDAC patients possible side effects are deemed acceptable due to the very limited number of possible treatment options and short overall survival which is usually only a year after diagnosis. If side effects become too debilitating, dose reduction can be considered or the patient can be withdrawn from study.

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

* Age between 18 and 65 years.
* Diagnosed with stable pancreatic cancer after standard of care treatment (defined as no detectable disease recurrence or disease progression on CT imaging within 6 weeks after completing standard of care treatment.
* Completed standard of care treatment.
* Bilirubin < 35 µmol/L (after drainage if applicable).
* Patient should be able to understand the content of the protocol and be able to perform all follow ups.
* Signed informed consent.

Exclusion criteria

* Previous malignancy (excluding non-melanoma skin cancer), unless no evidence of disease and diagnosed more than 2 years before diagnosis of pancreatic cancer.
* Pregnancy.
* Unable to draw blood for study purposes.
* Serious concomitant systemic disorders that would compromise the safety of the participant or their ability to complete the study, at the discretion of the investigator.
* Surgery, or other procedures (other than the pancreatic surgery) that have altered the gastrointestinal integrity which might influence uptake op Espera C®.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	24
Type:	Anticipated

Ethics review

Approved WMO

Date:	13-03-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL71487.078.19