The effects of micellar curcumin (Espera) on the immune function of pancreatic cancer patients.

Published: 28-06-2018
Last updated: 12-04-2024

Determine whether micellar curcumin (Espera®) is able to improve the Systemic Immune Inflammation index in operable PDAC patients OR (metastasized) pancreatic cancer patients with stable disease after standard of care treatment.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Exocrine pancreas conditions
Study type	Interventional

Summary

ID

NL-OMON46507

Source
ToetsingOnline

Brief title
Effects of curcumin on the immunesystem in pancreatic cancer.

Condition

- Exocrine pancreas conditions
- Gastrointestinal neoplasms malignant and unspecified

Synonym
pancreatic cancer, pancreatic ductal adenocarcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Leveronderzoek
Source(s) of monetary or material Support: Ministerie van OC&W,Fit for me,FitForMe

Intervention

Keyword: curcumin, immune function, pancreatic cancer

Outcome measures

Primary outcome

Determine whether micellar curcumin (Espera®) is able to improve the SIII index

in operable PDAC patients OR PDAC patients with stable (metastatic) disease

after standard of care treatment.

Secondary outcome

There will be no secondary objective for patient group 1: (borderline)

resectable pancreatic cancer patients.

For patient group 2: pancreatic cancer patients with stable (metastatic)

disease after standard of care we will determine if there is a time-trend in

SIII changes by using repeated measurements.

Study description

Background summary

Patients diagnosed with pancreatic cancer have a poor survival. The presence of pancreatic cancer is known to affect the functionality of the immune system. In addition to the common factors affecting the prognosis of cancer patients, individual differences in immune factors among patients also affect prognosis. The majority of tumors have an inflammatory component which can either promote cancer growth, e.g., *cancer related inflammation* or inhibit cancer progression, e.g., *cancer immune surveillance*. The systemic inflammation immune index (SIII) represents systemic inflammatory responses and can be used to indicate the host inflammatory and immune status in resected cancer patients. In this study we would like to investigate whether we are able to improve the SIII of PDAC patients by prescribing the oral food supplement curcumin. Curcumin can modulate the immune system of pancreatic cancer patients

by restoring the functional lymphocytes (T cell populations) and skewing the immune response from an unfavorable to a favorable immune response. This increased population of functional T cells will lead to a decrease in the SIII, which in turn is associated with a more favorable disease outcome.

Study objective

Determine whether micellar curcumin (Espera®) is able to improve the Systemic Immune Inflammation index in operable PDAC patients OR (metastasized) pancreatic cancer patients with stable disease after standard of care treatment.

Study design

Exploratory single centre, randomized, open label study.

Intervention

Investigational treatment consist of oral micellar curcumin (Espera®). Resectable patients will receive 2dd2 capsules (18 mg micellar curcumin/capsule) for a period of at least 2 weeks prior to their surgical resection. The control group will not undergo any intervention.

Patients with stable disease will receive 2dd2 capsules (18 mg micellar curcumin/capsule) for a period of 4 weeks. Patients will continue to receive oral micellar curcumin (Espera®) during 12 week periods until no further benefit can be determined (defined as SIII >900, SIII >900 and no significant decrease (<20%) or disease recurrence/disease progression on imaging). In addition these patients will undergo additional blood sampling.
The control group will not receive curcumin treatment but will undergo 3 additional blood samplings during a 12 week period.

Study burden and risks

Resectable patients will undergo no additional blood sampling procedures compared to their standard of care. Patients with stable (metastatic)disease will undergo an additional blood sampling procedure after every 4 weeks of treatment.

Patient safety is assessed during the study. At each visit patients are checked for adverse events and vital signs. In addition, regular CT scans will be performed during standard of care to keep track of tumor characteristics during the treatment period, however no additional CT scans will be performed. Any remaining risks are deemed acceptable since the treatment options for these patient groups are limited and overall survival is usually only a year after

diagnosis.

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 * 18 years.
* Diagnosed with resectable or borderline resectable pancreatic cancer (patientgroup 1) OR stable (metastatic)disease after standard of care treatment (patientgroup 2).
* An SIII of 900 or higher.
* Bilirubin <35 µmol/L(after drainage if applicable).
* Planned surgical treatment (patientgroup 1) OR completed standard of care treatment (patientgroup 2).
* Signed informed consent.

Exclusion criteria

* Prior radiotherapy, chemotherapy, or resection for pancreatic cancer if included in patientgroup 1.
* 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 patient or his/her ability to complete the study, at the discretion of the investigator.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-07-2018
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	28-06-2018
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	NL64789.078.18