The effect of curcumin and genistein in CF patients with a class III mutation

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23234

Source
NTR

Brief title
TICTAC

Health condition

Cystic Fibrosis

Sponsors and support

Primary sponsor: University Medical Center Utrecht (UMCU)
Source(s) of monetary or material Support: ZON-MW, The Netherlands Organization for Health Research and Development

Intervention

Outcome measures

Primary outcome

Sweat chloride concentration (SCC) before and after treatment with curcumin and genistein.

Secondary outcome

• Correlation between individual curcumin+genistein induced CFTR function in vitro (organoid-based measurements) and in vivo treatment effect (lung function, SCC);

• The CFTR stimulating ability of the concentration of curcumin+genistein in the patient's blood samples, examined by in vitro testing (in the organoid model). We will also determine the plasma levels of curcumin and genistein, only after treatment with curcumin and genistein.

• Pulmonary function (%FEV1) and airway resistance (Rint and bodybox);

• BMI (=weight (in Kg)/Length2 (in cm));

• Quality of life (measured with CFQ-questionnaire);

• Bile salt measurements in plasma and the feces;

• Elastase measurements in the feces.

Study description

Background summary

We hypothesized that treatment with a combination of the natural food components curcumin and genistein can lead to a therapeutic level of restoration of the CFTR protein channel activity in patients with a class III, S1251N gating mutation.
Measurements in vitro (in organoids) can predict the individual treatment efficacy of curcumin and genistein. Primary objective is to investigate the therapeutic potential of the natural food components curcumin and genistein in Dutch CF patients carrying the S1251N gating mutation.
A secondary objective is to evaluate the correlations between individual curcumin+genistein induced CFTR function in vitro and the in vivo treatment effect. Another secondary objective is to evaluate the CFTR stimulating ability of the concentration of curcumin+genistein in the patient's blood samples, examined by in vitro testing.Children, adolescents and adults with Cystic Fibrosis who are 6 years or older and have a compound/S1251N class III gating mutation will receive curcumin and genistein in a dosage that is based on their weight during 8 weeks.. Main study parameter will be sweat chloride concentrationbefore and after receiving curcumin+genistein.

Study objective

Treatment with a combination of the natural food components curcumin and genistein can lead to a therapeutic level of restoration of the CFTR protein channel activity in patients with a class III, S1251N gating mutation.. Measurements in vitro can predict the individual treatment efficacy of curcumin and genistein.

Study design

Before and after the use of curcumin+genistein

Intervention

All patients will use the feeding supplements curcumin and genistein in a dosage that is based on their weight, during the first 8 weeks.

Contacts

Public
Wilhelmina Kinderziekenhuis
Huispostnummer KH 01.419.0
Postbus 85090
S. Michel
Utrecht 3508 AB
The Netherlands
+31 (0)88 75 537 25
Scientific
Wilhelmina Kinderziekenhuis
Huispostnummer KH 01.419.0
Postbus 85090
S. Michel
Utrecht 3508 AB
The Netherlands
+31 (0)88 75 537 25

Eligibility criteria

Inclusion criteria

• CFTR genotype compound/ S1251N

• Had a rectal biopsy to produce an organoid

• Male and female patients, aged 6 years or older on the date of informed consent or, where appropriate, date of assent

• Signed informed consent form (IC), and where appropriate, signed assent form

Exclusion criteria

• Severe acute exacerbation or pulmonary infection during last four weeks (needing intravenous treatment and/or systemic corticosteroids);

• Use of curcumin and or genistein at start or within four weeks prior to start of the study.

• Participation in another drug-investigating clinical study at the start or within four weeks prior to the start;

• Known cholelithiasis;

• Inability to follow instructions of the investigator.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2014
Enrollment:	10
Type:	Actual

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 40933
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4371
NTR-old	NTR4585
CCMO	NL48122.041.14
OMON	NL-OMON40933

Study results