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

Gepubliceerd: 07-05-2014 Laatst bijgewerkt: 19-03-2025

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...

Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23234

Bron
NTR

Verkorte titel
TICTAC

Aandoening

Cystic Fibrosis

Ondersteuning

Primaire sponsor: University Medical Center Utrecht (UMCU)
Overige ondersteuning: ZON-MW, The Netherlands Organization for Health Research and Development

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

Before and after the use of curcumin+genistein

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Wilhelmina Kinderziekenhuis
Huispostnummer KH 01.419.0

Postbus 85090
S. Michel
Utrecht 3508 AB
The Netherlands
+31 (0)88 75 537 25

Wetenschappelijk

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

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-07-2014
Aantal proefpersonen:	10
Type:	Werkelijke startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 40933
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten