MyCyFAPP PERT model

Gepubliceerd: 29-02-2016 Laatst bijgewerkt: 19-03-2025

In the paediatric age, secondary malnutrition to Cystic Fibrosis (CF) has a negative impact in the patients clinical evolution for its repercussion, among others, on the digestive and absorptive functions and the appetite. Maintaining an adequate...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24050

Bron
NTR

Verkorte titel
MyCyFAPP

Aandoening

Cystic fibrosis

Ondersteuning

Primaire sponsor: Erasmus Medical Center -Sophia Children's Hospital Rotterdam
Overige ondersteuning: European Union (HORIZON 2020; projectnumber 643806)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main study parameter is to assess, how much the final fat in stools deviates from the normal concentration (6g/24h) after applying the individual correction factor (ICF).

Toelichting onderzoek

Achtergrond van het onderzoek

This study is part of a large HORIZON 2020 project Innovative approach to self-management and social welfare of Cystic Fibrosis patients in Europe: development, validation and implementation of a telematics tool)

Doel van het onderzoek

In the paediatric age, secondary malnutrition to Cystic Fibrosis (CF) has a negative impact in the patients clinical evolution for its repercussion, among others, on the digestive and absorptive functions and the appetite. Maintaining an
adequate nutritional status is an indispensable aspect of the CF treatment, since it directly affects the quality of life, the lung function and the survival. Pancreatic insufficient patients require supplementation with exogenous pancreatic enzyme therapy (PERT), with the aim to reduce the fecal losses of fat, protein and biliary acids and the deficit of fatsoluble vitamins associated to this disease. It is crucial that the administration of pancreatic extracts is in the correct dose and, moreover, adapted to each moment and each meal.

The main objective in the first approach is to obtain a mathematical predictive model (MPM) adapted to each patients' gastrointestinal conditions that calculates the optimal amount of enzymatic supplements for the optimal fat digestion of any food or meal. So for each patient an individual correction factor (ICF)
will be obtained. Afterwards, in a second step, the objective is to validate the MPM by assessing how much the final fat in stools after applying the ICF deviates from the optimal value (<6g of fat/24h).

The MPM would be eventually implemented into a mobile APP, and together with an enzyme requirements database for different food products and meals digestion, will be able to, through a calculation algorithm, predict the amount of PERD required for a specific meal, and taking into account individual needs for correction of the dose. This will allow for self-management of this essential therapy regardless of time and place.

Onderzoeksopzet

The study consists of 3 parts of each 2 x 1 day.
Part 1:

- Follow a test diet with a fixed PERT dose (theoretical dose).

- Collection of feces that is marked by intake of color capsules.

- Keeping a nutritional diary.

Part 2:

- same as part 1 except the use of a PERT dosage that takes the individual correction factor (as obtained by part 1)
into account.

Part 3:

- same as part 2, so with a personal PERT dosage, but follow of a free diet

The 3 parts will take place during a period of 9 months.

Onderzoeksproduct en/of interventie

The interventions consist of following a test diet, the use of PERT (own capsules, test dose), the collection of feces that is marked by the intake of color capsules and keeping a nutritional diary. These interventions take place during 3 x 2 weekends.

Contactpersonen

Publiek

Erasmus MC - Sophia Children's Hospital

JM Hulst
Wytemaweg 80

Rotterdam 3015 CN
The Netherlands
tel: 0107036049

Wetenschappelijk

Erasmus MC - Sophia Children's Hospital

JM Hulst
Wytemaweg 80

Rotterdam 3015 CN
The Netherlands
tel: 0107036049

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Diagnosis of CF as evidenced by one or more clinical feature consistent with the CF phenotype or positive CF
newborn screen AND one or more of the following criteria:

a) A documented sweat chloride ¡Ý 60 mEq/L by quantitative pilocarpine iontophoresis (QPIT)

b) A documented genotype with two disease-causing mutations in the CFTR gene

2. Informed consent by parent or legal guardian; assent for children from age 12 years on

3. Having pancreatic insufficiency (stool elastase < 200 mcg/g stool) and using PERT

4. Age ¡Ý 12 months and < 18 years at Screening visit

5. Stable clinical status at least two weeks before signing the informed consent.

6. Patients¡¯ capacity and willingness to fulfill the meal test and the faeces collection during the weekend

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Acute infection associated with decreased appetite or fever at time of run-in visit

2. Acute abdominal pain necessitating an intervention at time of run-in visit

3. Severe cholestasis (direct bilirubin increase above 2 mg/dL with respect to the normal limit for age).

4. FEV1 <40% for age, gender, weight and height.

5. Severe hypoalbuminemia (albumin in blood <2.5g/mL).

6. Hospitalisation or intravenous antibiotics <2 weeks before signing the informed consent.

7. Changes in the usual treatment (prokinetics, antiacids, H2 blockers and antibiotics) < 2 weeks before signing the
informed consent.

8. Presence of alterations that, according to the investigator consideration, could jeopardise the safety of the patient.

9. Hypersensibility or adverse reactions to the enzymatic supplements.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	13-03-2016
Aantal proefpersonen:	12
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46193
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5649
NTR-old	NTR5765
CCMO	NL55266.078.16
OMON	NL-OMON46193

Resultaten