TAPAS study in patients with CF

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Inhalation of once daily double dose of inhaled tobramycin targeted to the small airways by the Akita (1x 300 mg instead of 2x 150 mg) is more effective in reducing small airways obstruction compared with standard of treatment: twice daily...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27235

Bron
NTR

Verkorte titel
TAPAS study in patients with CF

Aandoening

Cystic Fibrosis
Tobramycin

Ondersteuning

Primaire sponsor: Erasmus Medical Center - Sophia Children's Hospital
Overige ondersteuning: Erasmus Medical Center - Sophia Children's Hospital

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

change in FEF75 (Z-score and L/s) after 4 weeks of targeted treatment

Toelichting onderzoek

Doel van het onderzoek

Inhalation of once daily double dose of inhaled tobramycin targeted to the small airways by the Akita (1x 300 mg instead of 2x 150 mg) is more effective in reducing small airways obstruction compared with standard of treatment: twice daily nebulization of standard dose using a standard nebulizer (2x 300 mg).

Onderzoeksopzet

There will be 4 study visits in the outpatient clinic. The first and third study visit will be at the start of the treatment months, the 2nd and 4th study visits will be at the end of the treatment months.

Onderzoeksproduct en/of interventie

Patients will nebulize tobramycin during 2 months in a cross-over setting: 1 month nebulization with the Akita nebulizer (once daily 300 mg tobramycin instead of twice daily 150 mg) and 1 month the recommended dose with their own nebulizer (twice daily 300 mg tobramycin). The two treatment months are seperated with a month without treatment as recommended for the treatment of a chronic pseudomonas infection.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Age ≥ 12 years

• Clinical diagnosis of CF and a positive sweat test or two CF-related mutations;

• Chronic Pa colonization requiring maintenance therapy with inhaled tobramycin, defined according to the Leeds criteria (>50% Pa positive airway cultures over last 12 months) 22;
• Small airways obstruction present on spirometry (defined as follows: dissociation between FVC and FEF75 values (i.e. FEF75 at least 20% (absolute percent predicted) less than FVC);

• Ability to breathe through a mouthpiece and to use the inhaler;

• Ability to perform lung function tests;

• Written informed consent (12-18 years: child and parents; ≥ 18 years: patient).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Severe acute exacerbation of pulmonary infection (needing intravenous treatment) within one month prior to start or during the study;

• Known impaired kidney function (estimated creatinine clearance < 60 ml/min);

• Known aminoglycoside hypersensitivity;
• Start of nephrotoxic or ototoxic drugs, e.g. aminoglycosides, within 1 month prior to start or during the study;

• Therapy (e.g. furosemide) or disease which may complicate evaluation of the study protocol, as judged by the investigator;

• Participation in another drug-investigating clinical study at the start or within 1 month prior to the start;

• Inability to follow instructions of the investigator.

• Use of Tobramycin Inhalation Powder as part of the maintenance therapy

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-05-2015
Aantal proefpersonen:	26
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	04-05-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5079
NTR-old	NTR5211
Ander register	: MEC-2014-260

Resultaten