Intralesional Steroid Injections to Prevent Refractory Strictures in Patients with Esophageal Atresia – a randomized controlled trial (STEPS-EA)

Gepubliceerd: 21-01-2019 Laatst bijgewerkt: 15-05-2024

We hypothesize that the application of intralesional steroid injections in esophageal strictures in children with esophageal atresia could prevent the occurrence of refractory strictures and reduce the total number of dilatations by 50% in this...

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

Samenvatting

ID

NL-OMON26384

Bron
NTR

Verkorte titel
STEPS-EA trial

Aandoening

esophageal atresia, strictures, slokdarmatresie, stricturen, stenose

Ondersteuning

Primaire sponsor: Erasmus MC - Sophia Children's Hospital
Overige ondersteuning: ERNICA

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome parameter is the total number of dilatations per patient within 28 days interval required during the study period, defined as the period from the day of the 3rd dilatation until 6 months later.

Toelichting onderzoek

Achtergrond van het onderzoek

This is an international multicentre single-blinded randomised controlled trial with two arms: injection prior to balloon dilatation and single dilatation without any injection. One hundred and ten children with EA type C will be recruited within the framework of an European Reference Network. After the indication for dilatation has been determined with an oesophagram, the intervention will take place at time of the 3rd dilatation. During a follow up period of six months, patients will undergo an oesophagram, length and weight will be measured, a scalp hair sample will be collected and parents will be invited to fill out three questionnaires. The primary outcome parameter is the total number of dilatations within 28 days interval needed per patient during the study period. Secondary outcome parameters include the level of dysphagia, the luminal esophageal diameter and stricture length as measured on the oesophagrams, influence of co-medication, systemic effects of TAC (cortisol levels, length and weight) and the cost-effectiveness. The primary outcome parameter will be analysed with a linear-by-linear chi-square association test.

Doel van het onderzoek

We hypothesize that the application of intralesional steroid injections in esophageal strictures in children with esophageal atresia could prevent the occurrence of refractory strictures and reduce the total number of dilatations by 50% in this population.

Onderzoeksopzet

Outcome: total number of dilatations, time point: 6 months
Outcome: interval untill last dilatation, time point: 6 months
Outcome: Montreal Feeding Scale, time point: 6 months
Outcome: change in diameter en stricture length, time point: 3 weeks
Outcome: use of co-medication, time point: 6 months
Outcome: cortisol level, time point: 6 months
Outcome: total costs, time point: 6 months

Onderzoeksproduct en/of interventie

Injection with 10mg triamcinolone acetonide (1mL Kenacort-A 10)

Contactpersonen

Publiek

Erasmus MC - Sophia Children's Hospital
Chantal ten Kate

+31107036116

Wetenschappelijk

Erasmus MC - Sophia Children's Hospital
Chantal ten Kate

+31107036116

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Children with EA type C who underwent primary anastomotic surgery within the first days of life
- Age >3 months at the time of the 3rd dilatation
- In need of a 3rd dilatation
- Written informed consent by both parents or legal representatives, if applicable

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Age <3 months
- Known inability from previous dilatations to use an endoscope with a size of 5.8 mm
- No parental written informed consent

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	11-01-2019
Aantal proefpersonen:	110
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
The data that support the findings of this study will be available from the corresponding author upon reasonable request.

Ethische beoordeling

Positief advies

Datum:	21-01-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50430
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7484
NTR-old	NTR7726
CCMO	NL65364.078.18
OMON	NL-OMON50430

Resultaten