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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26384

Source
Nationaal Trial Register

Brief title
STEPS-EA trial

Health condition

esophageal atresia, strictures, slokdarmatresie, stricturen, stenose

Sponsors and support

Primary sponsor: Erasmus MC - Sophia Children's Hospital
Source(s) of monetary or material Support: ERNICA

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

1) Total number of dilatations within the study period, regardless of the interval.

2) Interval (in weeks) between the start of the study and the last dilatation procedure within the study period.

3) Montreal Feeding Scale (in Dutch Screeningslijst Eetgedrag Peuters (SEP)), measured at the end of the follow up period.

4) The relative change in maximal luminal diameter after the 3rd dilatation compared to the diameter before the 3rd dilatation.

5) The relative change in length of the esophageal stricture after the 3rd dilatation compared to the length before the 3rd dilatation.

6) The use of co-medication (e.g. antacids) during the study period.

7) The mean cortisol level over the first three months after the 3rd dilatation, measured in a hair sample taken at the end of the follow up period.

8) Total costs of the treatment, including medical and non-medical costs.

9) Incremental costs per refractory stricture prevented and incremental costs per additional dysphagia-free patient.

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

- 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

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-01-2019
Enrollment:	110
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

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

Ethics review

Positive opinion

Date:	21-01-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50430
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results