Intralesional steroid injections to prevent refractory strictures in patients with esophageal atresia - a randomized controlled trial

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This study has been transitioned to CTIS with ID 2023-504905-36-00 check the CTIS register for the current data. The primary objective is to find out whether ISI in children with EA can prevent refractory strictures from developing and consequently…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal stenosis and obstruction
Study type	Interventional

Summary

ID

NL-OMON50430

Source
ToetsingOnline

Brief title
STEPS-EA trial

Condition

- Gastrointestinal stenosis and obstruction

Synonym
narrowing esophagus, stricture after esophageal atresia

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: esophageal atresia, intralesional steroid injections, strictures

Outcome measures

Primary outcome

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

Secondary outcome

The secondary outcome parameters are:

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

Esophageal atresia (EA) is a rare congenital anomaly. The most frequent postoperative complication is an anastomotic stricture with a reported incidence of 18-60% in the first year of life. A refractory anastomotic stricture is defined as an anatomic restriction without endoscopic inflammation that results in dysphagia after >=5 dilatation procedures at maximally 4-week intervals. Refractory strictures require multiple dilatations (with risk of perforation) under general anesthesia and thus represent a large burden for both patients and parents. Intralesional steroid injections (ISI) are a possible additional treatment to dilatation and promising results have been reported in retrospective studies in children with caustic and anastomotic strictures. In addition, four randomized controlled trials (RCTs) have been published on ISI in adult patients with esophageal strictures, with other underlying diagnoses than EA. Beneficial effects include fewer dilatation procedures needed, larger esophageal diameter and relief of dysphagia. We hypothesize that this approach could prevent refractory strictures in children with EA and reduce the total number of dilatations by 50%. No RCTs with ISI have been conducted in patients with EA.

Study objective

This study has been transitioned to CTIS with ID 2023-504905-36-00 check the CTIS register for the current data.

The primary objective is to find out whether ISI in children with EA can prevent refractory strictures from developing and consequently can reduce the total number of dilatations needed within 28 days interval.

Study design

Multicenter single-blind randomized controlled trial. One hundred and ten children with EA type C will be recruited in a 3-year period, within the framework of an European Reference Network. The intervention will take place at time of the 3rd dilatation. After the 3rd dilatation, all patients will undergo an esophagram. After a follow up period of six months, a scalp hair sample will be taken and all parents are invited to fill out the Montreal Feeding Scale and the iMTA Productivity Cost Questionnaire (iPCQ). Children will be measured and

weighed at 2-3 weeks, 3 months and 6 months after the 3rd dilatation.

Intervention

Children assigned to the intervention group will be treated with ISI preliminary to the 3rd dilatation. Children assigned to the control group will undergo dilatation without any injections.

Study burden and risks

The risks and burden are small. Esophageal steroid injections can potentially cause adrenal suppression, perforation, intramural infection, candida infection, mediastinitis and pleural effusion. However, previous studies of ISI in children reported no adverse events related to the steroid injections. The burdens of filling out the questionnaires and taking a scalp hair sample are negligible. The potential reduction in the number of anesthetic procedures needed for dilatations outweighs the burden and radiation exposure of the second esophagram. The added value of the intervention in children from the age of 3 months has not yet been sufficiently studied.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- Children with EA type C who underwent primary anastomotic surgery
- Age >=3 months at the time of the 3rd dilatation
- In need of a 3rd dilatation
- Written informed consent by both parents or guardians 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 consen

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-10-2019
Enrollment:	30
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Kenacort
Generic name:	triamcinolonacetonide
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	11-12-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-01-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	23-12-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-03-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26384
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EU-CTR	CTIS2023-504905-36-00
EudraCT	EUCTR2018-002863-24-NL
CCMO	NL65364.078.18