Comparison of wound closure in sternotomy scars: intracutaneous closure versus Steristrip-S

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital cardiac disorders
Study type	Interventional

Summary

ID

NL-OMON33596

Source
ToetsingOnline

Brief title
Wound closure in sternotomy scars

Condition

- Congenital cardiac disorders
- Soft tissue therapeutic procedures

Synonym
scar, wound

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: intracutaneous, Steristrip-S, Sternotomy, wound closure

Outcome measures

Primary outcome

POSAS score

Secondary outcome

- PedsQL score (quality of life)

- pain

- relation between POSAS score and age

- relation between PedsQL score and POSAS score / pain

Study description

Background summary

Pain after cardiac surgery in adults is very common. The reported incidence of chronic post sternotomy pain (CPSP) varies from 21 to 56% according to various studies. Although frequently reported the etiology has not yet been clarified. By our knowledge this common pain syndrome has never been studied in children. In the Netherlands, each year at least 1200 - 1600 children are born with congenital heart malformations (source: www.rivm.nl). Most of these children need surgical correction for their disease. Sternotomy itself is worldwide in adults one of the most frequently performed operations. Sternotomy often leaves unsighty and painful scars in both adults and children, although objective scar assessment studies (like with POSAS) are very scarce. In the AMC/LUMC the sternotomy wound is closed either by intracutaneous stiches or by Steri-strip S. This last one has shown improved scar outcomes in sponsored studies. Quality of life is thereby an important item because heart disease and sternotomy will influence somebodies life in many ways. Unknown is whether age, postoperative pain or scarformation have influence on the perception of quality of life for the patient.

Study objective

The aim of this study is 1. to compare scarformation in two different operative

protocols in a prospective manner of children who undergo sternotomy because of cardiologic disease. 2. to differentioate scar pain from sternotomy pain. 3. to estimate quality of life of post sternotomy children.

Study design

A sample of 100 of children were recruited from the outpatient cardiothoracal clinic at AMC and LUMC. Patients were identified by review of the clinic schedule and medical charts. After informed consent and child assent was obtained from the participating families, they were asked to complete questionnaires at different stages:
- A= the PedsQL 4.0: quality of life
- B= the POSAS: scar assesment
- C= an additional pain and/or wound questionnaire
Before surgery (A,C); after surgery 4-6 weeks(C); 3 months (B,C); and 12 months (A,B,C)

Filling in the questionnaires was done by:
Children Parents
< 5 years 5-7 years 8-11 years 12-18 years
PedsQL - + + + +
PainQ - + - + +
POSAS - - - + +

When the POSAS is obtained:
The investigator also fills in the POSAS questionnaire and assesses scar sensitivity by striking a cotton wool swab over the scar and deep sternal pain by giving pressure on the sternum and drawing the pain location on a body scheme as well as taking a VAS score (smiley or numerical).

Intervention

Wound closure with steri-strip S or intracutaneous stiches by seeding.

N.B. Both wound closure methods are used at this moment dependent on the surgeon.

Study burden and risks

- There is no expected risk connected to this study
- There is hardly any burden, as no invasive investigation is done, no extra outpatient clinic visit.
- During the regular outpatient clinic visits, the patient is asked to fill in a questionnaire and undergoes a scar assessment including VAS score/comfort

scale

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

patients who undergo a primary sternotomy or a secondary sternotomy surgery in which the old scar is excised.

Exclusion criteria

patients who undergo an emergency surgery

patients who do not understand the dutch language

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2010
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	Steri-Strip S
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL25569.018.09