LTFU-STITCH trial

Suture **T**echniques to reduce the **I**ncidence of **T**he incisional **H**ernia, the **L**ong-**T**erm **F**ollow-**U**p of the **STITCH** trial

STUDY PROTOCOL

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PROTOCOL TITLE

Suture techniques to reduce the incidence of the incisional hernia, the long-term follow-up of the STITCH trial.

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TABLE OF CONTENTS

LIST OF ABBREVIATIONS AND RELEVANT DEFINITIONS

AE	**Adverse Event**
AR	**Adverse Reaction**
ASA	**American Society of Anesthesiologists**
AWF	**Abdominal Wall Function**
BMI	**Body Mass Index (kg/m^2)**
CA	**Competent Authority**
CCMO	**Central Committee on Research Involving Human Subjects; in Dutch: Centrale Commissie Mensgebonden Onderzoek**
DSMB	**Data Safety Monitoring Board**
EudraCT	**European drug regulatory affairs Clinical Trials**
GDPR	**General Data Protection Regulation; in Dutch: Algemene Verordening Gegevensbescherming (AVG)**
IB	**Investigator's Brochure**
IC	**Informed Consent**
IH	**Incisional Hernia**
METC	**Medical research ethics committee (MREC); in Dutch: medisch-ethische toetsingscommissie (METC)**
NRS	**Numeric Rating Scale**
QoL	**Quality of Life**
RCT	**Randomized Controlled Trial**
(S)AE	**(Serious) Adverse Event**
Sponsor	**The sponsor is the party that commissions the organisation or performance of the research, for example a pharmaceutical company, academic hospital, scientific organisation or investigator. A party that provides funding for a study but does not commission it is not regarded as the sponsor, but referred to as a subsidising party.**
UAVG	**Dutch Act on Implementation of the General Data Protection Regulation; in Dutch: Uitvoeringswet AVG**
WMO	**Medical Research Involving Human Subjects Act; in Dutch: Wet Medisch-wetenschappelijk Onderzoek met Mensen**

SUMMARY

Rationale: Incisional hernias (IH) are a frequent complication after abdominal surgery. Prevalence of an IH varies depending on the previous abdominal procedure but could be as high as 70% in high-risk patients after open surgery. To investigate different fascia closure techniques in the prevention of IHs, the STITCH trial (NCT01132209) was designed, a randomized controlled trial in which 560 patients were included between October 2009 and March 2012. They compared two different closure techniques for closure of a midline incision in adult patients undergoing an elective abdominal laparotomy. Patients were randomly assigned to the intervention group (small bites 5 mm x 5 mm) or the control group (large bites 1 cm x 1 cm). It showed that small bites are much more effective than large bites in the prevention of an incisional hernia when closing a midline incision.
So far, it has not been studied whether there is still a long-term difference in incidence of incisional hernia between the small bites and the large bites group.
Objective: The primary objective of this study is to determine the difference in incidence of IH between the small bites and the large bites group after 10 years of follow-up from time of randomization in the STITCH trial. The secondary objectives are to measure quality of life (QoL), body image and cosmetic results, and abdominal wall function through questionnaires and physical examination in those patients who are still alive.
Study design: Assessment of long-term follow-up (10-13 years) of a randomized controlled multicenter study based on retrospective review of patient files and relevant imaging of the entire trial population, as well as questionnaires and physical and radiological examination of patient who are still alive.
Study population: Of the 560 included patients in the original STITCH trial, 545 completed the 1-year follow-up.
Intervention (if applicable): Not applicable.
Main study parameters/endpoints: The primary outcome measure is the 10-year midline incisional hernia rate. The primary endpoint will be determined for the 545 patients of the original intention-to-treat population using Kaplan Meier analysis. In patients who died during follow-up, this will be evaluated by reviewing the available medical charts and radiological studies. CT-scans of the abdomen will be evaluated by the study-team. If CT imaging is not available, documented findings during physical examination by the relevant medical specialist will be considered. Patients being still alive with written informed consent to be contacted will be approached for their willingness to participate in this follow-up study, and after consent, we will reassess CT scans for an incisional hernia. All patients who are still alive and want to participate in this study will be asked to visit the hospital once for physical examination and an ultrasound of the abdominal wall.
Secondary outcome parameters include QoL and cosmetic outcome, Patients still alive with consent for participation will be sent the following questionnaires: MOS SF-36 and EQ-5D (QoL), Dresden Body Image Questionnaire (body image), Body Image Questionnaire (cosmesis), Hernia-Related Quality of Life Survey (abdominal wall function). Furthermore, readmission and surgical intervention rates related to midline IH will be determined for the entire study population.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Undergoing an ultrasound, physical examination and completing several questionnaires may be considered burdensome for the patient.

1. INTRODUCTION AND RATIONALE

Incisional hernias are a frequent complication after abdominal surgery. According to Korenkov et al. the definition of an incisional hernia is: ‘’any abdominal wall gap with or without bulge in the area of a postoperative scar perceptible or palpable by clinical examination or imaging’’(1). Prevalence of an incisional hernia varies depending on the previous abdominal procedure but could be as high as 70% in high-risk patients after open surgery (2-4). In the last decade, a total of over 84,000 patients in the Netherlands were diagnosed with an incisional hernia and more than 44,000 surgeries have been performed to repair the incisional hernia (5).

An incisional hernia can become symptomatic with the need for surgical repair. Symptoms such as pain, incarceration and decreased abdominal wall function (AWF) can occur. In addition, an incisional hernia can have a major impact on body image and quality of life (QoL) (6).

To investigate different fascia closure techniques in the prevention of incisional hernias, the STITCH trial was designed. The original STITCH study (NCT01132209), a randomized controlled trial in which 560 patients were included between October 2009 and March 2012, compared the two different closure techniques for closure of a midline incision (7). Adult patients undergoing elective abdominal laparotomy were randomly assigned to the intervention group or the control group. In the intervention group, the fascia was closed with small tissue bites of 5 mm every 5 mm and in the control group with large tissue bites of 1 cm every 1 cm. Of the 560 included patients in the original STITCH trial, 545 completed the 1-year follow-up. After 1-year follow-up, 21% of patients in the "large bites" group, the control group, had developed an incisional hernia versus 13% of patients in the intervention, "small bites" group. Thus, that showed that small bites are much more effective than large bites in the prevention of an incisional hernia when closing a midline incision (7). However, the majority of incisional hernias will become apparent and symptomatic in the first five years after surgery (8).

So far, it has not been studied whether there is still a long-term difference in incidence of incisional hernia between the small bites and the large bites group. We would like to propose assessment of the long-term follow-up of the patients included in the original STITCH trial to determine if the small bites are still effective in the long-term (10 year follow-up) in preventing incisional hernia.

2. OBJECTIVES

Primary Objective:

The primary objective of the original STITCH trial was reduction of the incidence of an incisional hernia after open, elective abdominal surgery. The primary objective of the present study is to determine the difference in incidence of incisional hernia between the intervention group and the control group of the original STITCH trial after 10 years of follow-up from the time of randomization,.

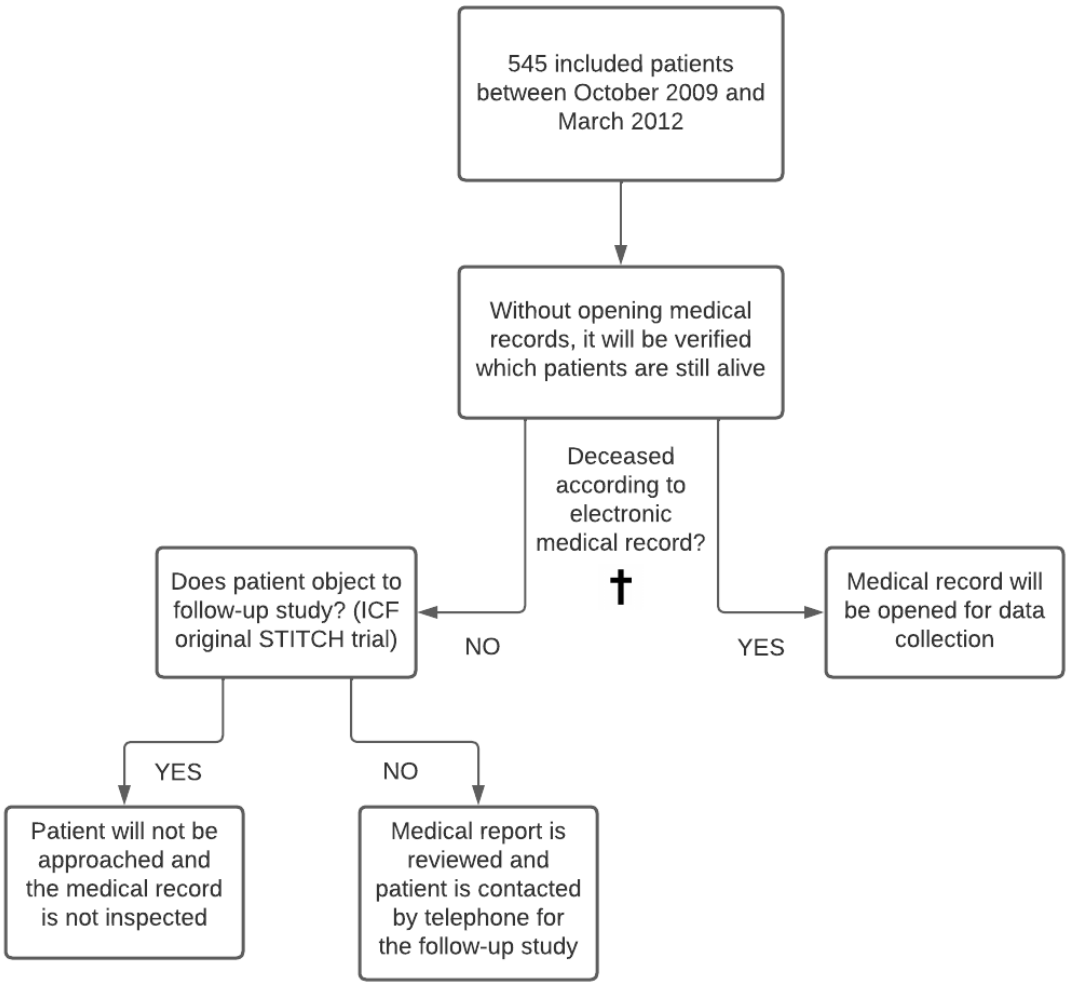
Secondary Objectives:

The secondary objectives of this follow-up study are to measure quality of life (QoL), body image and cosmetic results and abdominal wall function in those patients who are still alive.
In addition, all information is collected regarding the abdominal wall hernia (presence, location, duration, size, recurrence, repair) and other abdominal wall related complications such as: open abdomen, enterocutaneous fistula, wound problems, burst abdomen, number of abdominal reoperations, number of hospital admissions (and total days) with/without development of ileus.

STUDY DESIGN

The original STITCH trial (NCT01132209) was a multicenter double-blind prospective randomized controlled trial who randomly assigned 560 patients between October 2009 and March 2012 in the intervention group (small bites) or in the control group (large bites). Ultimately, 268 patients were included in the intervention group and 277 patients in the control group. A total of 545 patients.

This current study is a long-term (10-13 years) follow-up of the original STITCH trial.
The flowchart below graphically depicts the process of approaching the patients who were included in the original STITCH trial. On the original informed consent form of the STITCH trial patients were asked if they agreed to being contacted for a follow-up study after completion the original trial.



4. STUDY POPULATION

4.1 Population (base)

All 545 patients who were included in the original STITCH trial (NCT01132209) between October 2009 and March 2012.

4.2 Inclusion criteria

In order to be eligible to participate in this study, a subject must meet the following criteria:

- Available signed informed consent form for the original STITCH trial of the patients who are still alive. Of the patients who have died, the medical records are reviewed.
- Patients must give informed consent for the current study, the long-term follow-up of the STITCH trial.

4.3 Exclusion criteria

A potential subject who meets the following criteria will be excluded from participation in this study:

- Patients that on the original informed consent form of the STITCH trial, checked the box that they did not want to be approached for future follow-up studies.
- Patients who withdrew their informed consent during the original STITCH trial.

4.4 Sample size calculation

The original STITCH trial ended up with 545 patients completing the 1-year follow-up.

5. TREATMENT OF SUBJECTS

5.1 Investigational product/treatment

Not applicable as this is a follow-up study of a previous RCT. The surgical treatments have already taken place.

5.2 Use of co-intervention

Not applicable as no co-intervention is used in this study.

5.3 Escape medication

Not applicable. This study will not use any escape medication.

6. INVESTIGATIONAL PRODUCT

6.1 Name and description of investigational product

Not applicable as no investigational product is used in this study.

6.2 Summary of findings from non-clinical studies

Not applicable as no investigational product is used in this study.

6.3 Summary of findings from clinical studies

Not applicable as no investigational product is used in this study.

6.4 Summary of known and potential risks and benefits

Not applicable as no investigational product is used in this study.

6.5 Description and justification of route of administration and dosage

Not applicable as no investigational product is used in this study.

6.6 Dosages, dosage modifications and method of administration

Not applicable as no investigational product is used in this study.

6.7 Preparation and labelling of Investigational Medicinal Product

Not applicable as no investigational product is used in this study.

6.8 Drug accountability

Not applicable as no investigational product is used in this study.

7. NON-INVESTIGATIONAL PRODUCT

7.1 Name and description of non-investigational product(s)

Not applicable as no non-investigational product is used in this study.

7.2 Summary of findings from non-clinical studies

Not applicable as no non-investigational product is used in this study.

7.3 Summary of findings from clinical studies

Not applicable as no non-investigational product is used in this study.

7.4 Summary of known and potential and benefits

Not applicable as no non-investigational product is used in this study.

7.5 Description and justification of route of administration and dosage

Not applicable as no non-investigational product is used in this study.

7.6 Dosages, dosage modifications and method of administration

Not applicable as no non-investigational product is used in this study.

7.7 Preparation and labelling of Non Investigational Medicinal Product

Not applicable as no non-investigational product is used in this study.

7.8 Drug accountability

Not applicable as no non-investigational product is used in this study.

8. METHODS

8.1 Study parameters/endpoints

8.1.1 Main study parameter/endpoint

The primary outcome measure is the 10-year midline incisional hernia rate. The size (diameter) and location of the hernia will be documented.
In patients who died during follow-up, this will be evaluated by reviewing the available medical charts and radiological studies. CT-scans of the abdomen will be evaluated by the study-team. If CT imaging is not available, documented findings during physical examination by the relevant medical specialist will be considered. The CT scans of patients being still alive will be reassessed for an incisional hernia.

8.1.2 Secondary study parameters/endpoints

The secondary outcomes will be measured using five validating questionnaires. Quality of Life (QoL), body image, cosmetic results and abdominal wall function (AWF) will be reported from all patients who are still alive with consent for participation. Three of the five questionnaires have also been validated in a Dutch version. The other two were translated from English. The following measuring instruments will be used for this:

- Quality of Life
    - MOS SF-36: This questionnaire consists of 36 items. The item scores are summed to scale scores and transformed to a 100-point scale. A higher score indicates better health status(9).
    - EQ-5D; This questionnaire consists of a total of fourteen items. The answers can be converted to a total score representing the health profile(10).
- Body image: Dresden Body Image Questionnaire (DBIQ); consists of 35 items and five subscales (11).
- Cosmetic results: Body Image Questionnaire (BIQ); the questionnaire consists of ten items evaluating body image, cosmesis and self-confidence before and after surgery. The higher the score in the first five items, the lower the body image. The lower the score in items 6, 7 and 8, the lower cosmesis assessment. The last two items are about self-confidence before and after surgery where 1 is "not very confident" and 10 is "very confident." (12).
- AWF: Hernia-Related Quality of Life Survey (HerQLes); this questionnaire consists of twelve statements where the patient can choose from six options, how much they agree or disagree with the statement. The higher the score, the greater the burden of the abdominal wall(13).

8.1.3 Other study parameters

Demographic characteristics collected during randomization during the original trial are used for follow-up. This includes gender, age, length and weight (BMI), smoking history (yes or no), medical history and ASA class.

8.2 Randomisation, blinding and treatment allocation

Not applicable as no additional randomisation or blinding will be performed in this study. Patients had already been randomized at the time they were included in the original RCT.

8.3 Study procedure

Of patients still alive who want to participate in the follow-up study and patients who have died, the medical record and any available radiological imaging are reviewed retrospectively by members of the study team.

All patients who are still alive and want to participate in this study will be asked to visit the hospital once for physical examination and an ultrasound of the abdominal wall. Subsequently, all those patients will be asked to complete five validated questionnaires related to quality of life, cosmesis, body image and abdominal wall function. There is no set time after randomization in the original STITCH trial when the questionnaires should be completed. Indeed, this would mean that data collection would have to spread out over a few years which is not desirable.

After the physical examination and ultrasound are performed, the patient is given a brief explanation of the five questionnaires to be completed. The patient can choose whether to complete these questionnaires digitally at home or on paper at home (and return them free of charge).

8.4 Withdrawal of individual subjects

Subjects can leave the study at any time for any reason if they wish to do so without any consequences.

8.4.1 Specific criteria for withdrawal

Patients can withdraw their consent at any time during the study without having to give reason.

8.5 Replacement of individual subjects after withdrawal

Not applicable, all patients are already asked to participate so substitution is not possible when they withdraw their informed consent.

8.6 Follow-up of subjects withdrawn from treatment

Not applicable as patients do not receive treatment.

8.7 Premature termination of the study

Not applicable, the study will not be terminated prematurely.

9. SAFETY REPORTING

9.1 Temporary halt for reasons of subject safety

In accordance to section 10, subsection 4, of the WMO, the sponsor will suspend the study if there is sufficient ground that continuation of the study will jeopardise subject health or safety. The sponsor will notify the accredited METC without undue delay of a temporary halt including the reason for such an action. The study will be suspended pending a further positive decision by the accredited METC. The investigator will take care that all subjects are kept informed.

9.2 AEs, SAEs and SUSARs

9.2.1 Adverse events (AEs)

Not applicable, as this study does not involve an investigational medical product and this study is not subject to WMO.

9.2.2 Serious adverse events (SAEs)

Not applicable, as this study does not involve an investigational medical product.

9.2.3 Suspected unexpected serious adverse reactions (SUSARs)

Not applicable, as this study does not involve an investigational medical product.

9.3 Annual safety report

Not applicable, as this study does not involve an investigational medical product.

9.4 Follow-up of adverse events

Not applicable, as this study does not involve an investigational medical product.

9.5 Data Safety Monitoring Board (DSMB) / Safety Committee

Not applicable, since this follow-up study has a retrospective character.

10. STATISTICAL ANALYSIS

10.1 Primary study parameter(s)

We will analyse the primary outcome for the 545 patients using Kaplan Meier analysis and log-rank test to compare the two trial groups based on an intention-to-treat basis (7). Statistical analyses will be performed using IBM® SPSS® Statistics Version 29. In the case of missing data, a regression model is used to estimate the missing values.

10.2 Secondary study parameter(s)

Statistical comparison of quality of life, body image, cosmetic results and abdominal wall function between patient groups (small vs large bites technique and with or without incisional hernia) will be done by multilevel analysis (linear mixed-effects model with random effect for each patient) (7).

10.3 Other study parameters

Demographics and baseline characteristics will be reported using descriptive statistics.

10.4 Interim analysis (if applicable)

Not applicable, since no interim analysis is performed.

11. ETHICAL CONSIDERATIONS

11.1 Regulation statement

This study will be conducted in accordance with the principles of the Declaration of Helsinki (64th World Medical Association General Assembly, Fortaleza, Brazil, October 2013) This study has been exempted by the medical research ethics committee (MREC); in Dutch: Medisch Ethische Toetsings Commissie (METC). Following review of the protocol, the MREC concluded that this study is not subject to the Medical Research Involving Human Subjects Act (WMO). They concluded that the study is a medical/scientific research, but no patients are subjected to procedures or are required to follow rules of behavior.

11.2 Recruitment and consent

Patients who were included in the original STITCH trial and who are still alive will be approached by the study coordinator or the surgeon from the hospital they were included at the time, for participation in the follow-up study. Patients will only be approached if they have not checked the box on the Informed Consent Form of the original STITCH trial that they do not wish to be approached in the future for follow-up studies. Patients who indicated they had no objection to being approached will be contacted by telephone for participation and explanation of the study. If the patient approves, we will then send a subject information sheet with an informed consent form that allows the patient to make a well-informed and well-considered decision whether or not to participate in this follow-up study. The informed consent form can be returned free of charge by the patient when participation.

11.3 Objection by minors or incapacitated subjects

Not applicable as no minors or incapacitated subjects are included in this study.

11.4 Benefits and risks assessment, group relatedness

Undergoing an ultrasound, physical examination and completing several questionnaires may be considered burdensome for the patient.

11.5 Compensation for injury

As the study is not subject to the Medical Research Involving Human Subjects Act (WMO), the statutory obligation to provide insurance for subjects participating in medical research (article 7 of the WMO) also does not apply'.

11.6 Incentives

Patients will not receive any special incentives or additional treatment through participating in the study. Travel costs can be reimbursed.

12. ADMINISTRATIVE ASPECTS, MONITORING AND PUBLICATION

12.1 Handling and storage of data and documents

Research data will be stored in a Castor database and will be handled confidentially. Data will be coded with e.g. A01, A02, B01, etc (the letter depends on the site of the inclusion). Research data that can be traced to individual persons can only be viewed by authorized personnel. These persons are members of the research team, members of the health care inspection, and members of the Medical Research Ethics Committee. Data review may be necessary in order to ensure the reliability and quality of the research. The handling of personal data should comply with the EU General Data Protection Regulation and the Dutch Act on Implementation of the General Data Protection Regulation. (in Dutch: Uitvoeringswet AVG, UAVG). Data will be stored at least 15 years after date of publication.

12.2 Monitoring and Quality Assurance

The principal investigator, a project leader, or an independent person will monitor quality of the data in the database by checking correctness and completeness of data for a random selection of 10% of patients, with a minimum of 10 patients per participating hospital. Data regarding disease, disease severity, treatment, and outcome will be checked.

12.3 Amendments

Amendments are changes made to the research after a favourable opinion by the accredited METC has been given. All amendments will be notified to the METC that gave a favourable opinion.

12.4 Annual progress report

Not applicable, as this study will not be subject to the Medical Research Involving Human Subjects Act (WMO).

12.5 Temporary halt and (prematurely) end of study report

The investigator will notify the accredited METC of the end of the study within a period of 8 weeks. The end of the study is defined as the last patient's last visit.

The sponsor will notify the METC immediately of a temporary halt of the study, including the reason of such an action.

In case the study is ended prematurely, the sponsor will notify the accredited METC within 15 days, including the reasons for the premature termination. Within one year after the end of the study, the investigator/sponsor will submit a final study report with the results of the study, including any publications/abstracts of the study, to the accredited METC.

12.6 Public disclosure and publication policy

The publication policy of CCMO will be maintained. This statement contains the basic principles on CCMO's position on the disclosure/ publication of research results obtained from subjects involving

human subjects. It is the opinion of CCMO that the results of scientific research involving human subjects must be disclosed unreservedly.

Authors of potential publications following the present study will be determined by measure of contribution to the study protocol, study execution and manuscript synthesis, where the final decision of authorship is made by the Principal Investigator.

For publication of this follow-up study, the STROBE guideline will be followed (14).

13. STRUCTURED RISK ANALYSIS

13.1 Potential issues of concern

Not applicable, as this study does not involve an investigational or non-investigational product.

a. Level of knowledge about mechanism of action

Not applicable

b. Previous exposure of human beings with the test product(s) and/or products with a similar biological mechanism

Not applicable

c. Can the primary or secondary mechanism be induced in animals and/or in *ex-vivo* human cell material?

Not applicable

d. Selectivity of the mechanism to target tissue in animals and/or human beings

Not applicable

e. Analysis of potential effect

Not applicable

f. Pharmacokinetic considerations

Not applicable

g. Study population

Not applicable

h. Interaction with other products

Not applicable

i. Predictability of effect

Not applicable

j. Can effects be managed?

Not applicable

13.2 Synthesis

Not applicable, as this study does not involve an investigational or non-investigational product.

14. REFERENCES

1. Korenkov M, Neugebauer E. Comments on the letter from S. Petersen and K. Ludwig concerning our paper "Classification and surgical treatment of the incisional hernia. Results of expert meeting." Langenbeck's Arch Surg 386:65-73. Langenbecks Arch Surg. 2001;386(4):310-1.
2. Alnassar S, Bawahab M, Abdoh A, Guzman R, Al Tuwaijiri T, Louridas G. Incisional hernia postrepair of abdominal aortic occlusive and aneurysmal disease: five-year incidence. Vascular. 2012;20(5):273-7.
3. Borab ZM, Shakir S, Lanni MA, Tecce MG, MacDonald J, Hope WW, et al. Does prophylactic mesh placement in elective, midline laparotomy reduce the incidence of incisional hernia? A systematic review and meta-analysis. Surgery. 2017;161(4):1149-63.
4. Muysoms FE, Antoniou SA, Bury K, Campanelli G, Conze J, Cuccurullo D, et al. European Hernia Society guidelines on the closure of abdominal wall incisions. Hernia. 2015;19(1):1-24.
5. Open data van de Nederlandse zorgautoriteit [Internet]. 2022 [cited July 13th 2022]. Available from: https://www.opendisdata.nl.
6. van Ramshorst GH, Eker HH, Hop WC, Jeekel J, Lange JF. Impact of incisional hernia on health-related quality of life and body image: a prospective cohort study. Am J Surg. 2012;204(2):144-50.
7. Deerenberg EB, Harlaar JJ, Steyerberg EW, Lont HE, van Doorn HC, Heisterkamp J, et al. Small bites versus large bites for closure of abdominal midline incisions (STITCH): a double-blind, multicentre, randomised controlled trial. Lancet. 2015;386(10000):1254-60.
8. Jensen KK, Krarup PM, Scheike T, Jorgensen LN, Mynster T. Incisional hernias after open versus laparoscopic surgery for colonic cancer: a nationwide cohort study. Surg Endosc. 2016;30(10):4469-79.
9. MOS SF-36: Meetinstrumenten in de zorg; 2012 [Available from: https://meetinstrumentenzorg.nl/wp-content/uploads/instrumenten/SF-36-RAND-36-meetinstr.pdf.
10. Group E. EQ-5D - Gezondheidsvragenlijst 1990 [Available from: http://gertrudpijnenburg.nl/wp-content/uploads/2019/11/Gezondheid-vragenlijst-EQ5D.pdf.
11. Scheffers M, van Duijn MAJ, Bosscher RJ, Wiersma D, Schoevers RA, van Busschbach JT. Psychometric properties of the Dresden Body Image Questionnaire: A multiple-group confirmatory factor analysis across sex and age in a Dutch non-clinical sample. PLoS One. 2017;12(7):e0181908.
12. Dunker MS, Stiggelbout AM, van Hogezand RA, Ringers J, Griffioen G, Bemelman WA. Cosmesis and body image after laparoscopic-assisted and open ileocolic resection for Crohn's disease. Surg Endosc. 1998;12(11):1334-40.
13. Krpata DM, Schmotzer BJ, Flocke S, Jin J, Blatnik JA, Ermlich B, et al. Design and initial implementation of HerQLes: a hernia-related quality-of-life survey to assess abdominal wall function. J Am Coll Surg. 2012;215(5):635-42.
14. von Elm E, Altman DG, Egger M, Pocock SJ, Gotzsche PC, Vandenbroucke JP, et al. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies. Int J Surg. 2014;12(12):1495-9.