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Skin closure by subcuticular suture or skin stapling after elective hepatobiliary and pancreatic surgery: a single-center, open-label parallel randomized clinical trial

Submission date
13/01/2020

Recruitment status
No longer recruiting

Registration date
14/01/2020

Overall study status
Completed

Last Edited
16/01/2023

Condition category
Surgery

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Superficial surgical-site infection (sSSI) is a common complication after surgery that accounts for about 15% of all nosocomial infections and for nearly up to 38% of these in surgical patients. Furthermore, surgical site-infection is associated with a significant increase in both hospital admission days and healthcare-related cost. Additionally, surgical-site infection is closely related to postoperative morbidity and mortality. Therefore, strategies to prevent surgical-site infection are crucial to optimize surgical procedures and contain medical costs. Recently, it has been found that subcuticular suture might significantly decrease the sSSI rate in several digestive surgery fields (i.e. colorectal surgery). However, there are no prospective studies or randomized clinical trials assessing its impact on patients undergoing elective hepatobiliary and pancreatic surgery. The aim of this study is to assess the efficacy of subcuticular suture for the prevention of sSSI in this specific clinical scenario.

Who can participate?
Adult patients (i.e. older than 18 years old) undergoing either open or laparoscopic elective oncological or non-oncological hepatobiliary and pancreatic surgery.

What does the study involve?
The patients are randomly allocated to one of the two study treatment groups. One group includes patients in whom the skin closure is performed with conventional stapling. The second group includes patients undergoing subcuticular interrupted buried sutures for skin closure. Both study groups are followed for a period of 30 days.

What are the possible benefits and risks of participating?
Participants will potentially benefit from a decrease in morbidity due to a potential significant drop in sSSI rate. There are no expected significant risks from participating. There is no risk of major side effects related to the study procedures. Both subcuticular suture and stapling skin closure are widely performed in patients undergoing elective digestive surgery.

Where is the study run from?
Donostia University Hospital (Spain)

When is the study starting and how long is it expected to run for?
November 2019 to March 2022

Who is funding the study?
Department of Health (Basque Goverment) (Spain)

Who is the main contact?
Ignacio Aguirre-Allende MD
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Protocol number CLOSKIN-0001-2019

Study information

Scientific Title

Randomized clinical trial of prevention of superficial surgical-site infection in hepatobiliary and pancreatic surgery: skin closure by subcuticular suture vs. skin stapling

Acronym
CLOSKIN

Study objectives
sSSI represents a major healthcare problem in both developed and undeveloped countries. Several efforts have been made in the recent years in order to minimize sSSI impact on both patients and healthcare systems. However, sSSI still represents a prevalent complication in most digestive surgery departments across Europe.

Recent publications suggest that subcuticular suture skin closure might decrease significantly sSSI rate. Despite this evidence, there are no prospective studies or randomized clinical trials analysing this issue in elective oncological and non-oncological hepatobiliary and pancreatic surgery.

Hypothesis:
Skin closure by subcuticular suture significantly decreases superficial surgical-site infection (SSI-s) rate compared to standard skin stapling after elective oncological and non-oncological hepatobiliary and pancreatic surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/07/2019, Donostialdea Integrated Health Organisation Clinical Investigation Ethics Board (CEIC OSI Donostialdea, Clinical Epidemiology Unit. University Hospital Donostia. Begiristain Doktorea Pasealekua, 109. CP 20014, Donostia - San Sebastian, Spain; Tel: +34 (0)943 00 74 02; Email: mjose.velazquezzubicoa@osakidetza.eus), ref: HBP2019

Study design
Single-center interventional open randomized parallel clinical trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Superficial surgical-site infection (sSSI) in elective oncological and non-oncological hepatobiliary and pancreatic surgery

Interventions
Fascial closure will be performed according to the most recent evidence in order to minimize the risk of dehiscence and fascial site infection. For fascial closure continuous suture with synthetic absorbable monofilament material (i.e. 0 PDS-II, Ethicon or 0 Maxon, Medtronic) will be performed.

Patients will be assigned randomly and parallelly to one of the two treatment arms in a 1: 1 allocation ratio using a masked computer-generated sequence:
Group A (arm 1): skin closure with conventional surgical staples 1-1.5 cm interval (Medtronic)
Group B (arm 2): skin closure with interrupted subcuticular buried sutures using a synthetic absorbable material (i.e. 4-0 CAPROSYN, Ethicon or 4-0 no-coloured MONOSYN, Medtronic)

Both study groups are followed equally for a follow-up period of 30 days, and assessed for the primary endpoint.

Intervention Type
Procedure/Surgery

Primary outcome measure
sSSI rate measured by review of clinical records (i.e. medical history, daily medical records, complementary tests such as microbiological wound tests) at 30 days of follow-up

Secondary outcome measures
1. Incidence of sSSI measured using clinical records at 30 days of follow-up
2. Risk factors associated with sSSI measured using review of medical records, including baseline characteristics, previous medical background and variables related to the surgical procedure, at 30 days of follow-up
3. Hospital admission days measured using medical records at 30 days of follow-up

Overall study start date
30/06/2019

Completion date
01/03/2022

Eligibility

Key inclusion criteria
Adult patients undergoing elective oncological and non-oncological hepatobiliary and/or pancreatic surgery that have approved and signed the informed consent document

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
320 patients

Total final enrolment
370

Key exclusion criteria
1. Emergency surgery
2. Contaminated surgery according to WHO criteria and CDC definition for surgery
3. Active intraabdominal infectious process at the time of the surgery
4. Requirement for re-intervention due to a major postoperative intraabdominal complication
5. Non-compliance of the previously defined and standardized skin closure protocol including WHO recommendations for prevention of surgical site infection
6. Patients declined to participate

Date of first enrolment
31/01/2020

Date of final enrolment
01/12/2021

Locations

Countries of recruitment
Spain

Study participating centre
Donostia University Hospital - Biodonostia
Beguiristain Doktorea Pasealekua 109
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20014

Sponsor information

Organisation
Hospital Universitario Donostia

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
https://www.osakidetza.euskadi.eus/osi-donostialdea-hospital-universitario-presentacion/ab84-donoscon/es/

ROR
https://ror.org/04fkwzm96

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Funder Name
Osasun Saila, Eusko Jaurlaritzako

Alternative Name(s)
Departamento de Salud, Gobierno Vasco

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Spain

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. The researchers have planned to publish in open-access license agreement in order to enhance the dissemination of their study results.

A study protocol including methodology, statistical analysis, skin closure standardized procedure for both groups etc is available in Spanish since it is a protocol for local use. When the study is submitted for publication, the study protocol will be also submitted (prior translation by a language editing service) as additional material.

Intention to publish date

01/06/2022

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Ignacio Aguirre-Allende MD (ignacioaguirreallende@gmail.com) and Maialen Alkorta-Zuloaga MD (maialen.alkortazuloaga@osakidetza.eus). Type of available data: study robust data, fully anonymized, will be available for sharing upon request. Consent form of all participants was obtained in the patient enrollment to the study. Access criteria for sharing will include investigators aiming to perform studies in the field of surgical site-infection (mainly in hepatobiliary and pancreatic surgery) with enough clinical justification and always after receiving their Ethics Committee approval. Types of analyses: systematic reviews, meta-analysis. Anonymisation: all study data has been anonymised from the study start according to the study protocol and Ethics Committee Guidelines and Requirments. Thus, only fully anonymized robust data will be shared. In case of ethical or legal doubts or discrepancies with the request, the investigators will request the approval of their own Ethics Committee before sharing any data.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		13/01/2023	16/01/2023	Yes	No