ISRCTN27483786 https://doi.org/10.1186/ISRCTN27483786

Minimally invasive versus open pancreatoduodenectomy (surgery to remove the head of the pancreas, duodenum, gallbladder and other nearby tissues) for premalignant and malignant disease; Robotic versus open pancreatoduodenectomy (surgery to remove the head of the pancreas, duodenum, gallbladder and other nearby tissues) in patients with pancreatic head cancer (DIPLOMA-2x2)

Submission date
06/01/2022

Recruitment status
Recruiting

Registration date
11/01/2022

Overall study status
Ongoing

Last Edited
14/04/2025

Condition category
Surgery

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims

For patients with a (pre-)malignant pancreatic or periampullary (head of the pancreas) tumor, a pancreatoduodenectomy (surgery to remove the head of the pancreas, duodenum, gallbladder and other nearby tissues) is the only treatment with curative intent. A pancreatoduodenectomy is a complex operation with high technical difficulty and challenging postoperative management. Despite major improvements in the last decade, pancreatoduodenctomy remains associated with considerable perioperative morbidity (illness around the time of surgery), strongly impacting the patient's quality of life and healthcare resources. Minimally invasive pancreatoduodenectomy (MIPD), both robot-assisted and laparoscopic (keyhole surgery), has gained popularity in the last decade and reduces surgical trauma as compared to open pancreatoduodenectomy (OPD), aiming for faster recovery and improved outcomes. However, MIPD is associated with higher costs and a longer learning curve, and there have been conflicting results with regard to postoperative complications compared to OPD. As MIPD is increasingly being used in clinical practice worldwide, a randomized controlled trial (RCT) comparing MIPD to the open approach is needed to demonstrate that MIPD offers improved outcomes that justify the high cost, longer operative times, and steep learning curve.

Therefore, the aim of this study is to compare the outcomes of MIPD (both robotic and laparoscopic) with OPD for premalignant and malignant disease. The study is designed to primarily investigate the safety of MIPD (both robotic and laparoscopic) in terms of morbidity (illness) and mortality (death), and furthermore to assess if MIPD is superior to OPD in terms of time to functional recovery.

Who can participate?
Patients aged over 18 years who require pancreatoduodenectomy for resection of premalignant or malignant disease.

What does the study involve?
Participants are randomly allocated to either minimally invasive or open surgery. After surgery, patients receive a large abdominal dressing to mask their treatment by covering all incisions. This abdominal dressing is removed when recovery is complete on day 5 after the operation or for medical reasons, such as suspicion of a wound infection. Participants will be asked to wear a Fitbit™ Inspire 2 watch from before surgery up to 90 days after surgery. Participants complete quality of life questionnaires before surgery and at 1, 3 and 6 months after surgery. Survival rates are calculated for 1 and 3 years after the surgery.

What are the possible benefits and risks of participating?
Minimally invasive surgery may reduce the time to functional recovery, length of hospital stay and improve short-term quality of life, with similar postoperative morbidity rates. All centers have experience of more than 60 minimally invasive procedures before the study. There are no added risks.

Where is the study run from?
1. Amsterdam UMC (Netherlands)
2. Fondazione Poliambulanza Istituto Ospedaliero (Italy)

When is the study starting and how long is it expected to run for?
July 2020 to December 2026

Who is funding the study?
1. Amsterdam UMC (Netherlands)
2. Fondazione Poliambulanza Istituto Ospedaliero (Italy)
3. Intuitive Surgical Inc. (USA)

Who is the main contact?
1. Prof. Marc G. Besselink, m.g.besselink@amsterdamumc.nl
2. Prof. Mohammed Abu Hilal, abuhilal9@gmail.com

For DIPLOMA-2x2:
Background and study aims
For patients with a cancer in the pancreatic head (pancreatic ductal adenocarcinoma [PDAC] and distal cholangiocarcinoma [DCC]), a pancreatoduodenectomy (surgery to remove the head of the pancreas, duodenum, gallbladder and other nearby tissues) is the only treatment with curative intent. A pancreatoduodenectomy is a complex operation with high technical difficulty and challenging postoperative management. Despite major improvements in the last decade, pancreatoduodenctomy remains associated with considerable perioperative morbidity (illness around the time of surgery), strongly impacting the patient’s quality of life and healthcare resources. Robot-assisted pancreatoduodenectomy (RPD) has gained popularity in the last decade. The safety of the robotic approach has recently been confirmed with comparable

postoperative complications and enhanced postoperative recovery compared to open pancreatoduodenectomy (OPD). However, studies in gynecology and colorectal surgery showed that minimally invasive surgery was inferior in terms of radicality in patients with malignant disease. Hence, the oncological safety of RPD as compared to OPD remains to be determined. Therefore, the aim of this study is to compare the oncological outcome of RPD with OPD for cancer in the pancreatic head (PDAC and DCC). The study is designed to primarily investigate the radicality (R0 resection rate), and furthermore to assess if RPD is superior to OPD in terms of time to functional recovery in patients with cancer in the pancreatic head.

Who can participate?
Patients aged over 18 years who require pancreatoduodenectomy for resection of PDAC or DCC.

What does the study involve?
Participants are randomly allocated to either robot-assisted or open surgery. After surgery, patients receive a large abdominal dressing to mask their treatment by covering all incisions. This abdominal dressing is removed when recovery is complete on day 5 after the operation or for medical reasons, such as suspicion of a wound infection. Participants complete quality of life questionnaires before surgery and at 1, 3, 6 months and 1, 3, and 5 years after surgery. Survival rates are calculated for 1, 3, and 5 years after the surgery.

What are the possible benefits and risks of participating?
Robot-assisted surgery may reduce the time to functional recovery, length of hospital stay, and the time to start adjuvant therapy, with similar postoperative morbidity rates. All centers have experience of more than 60 minimally invasive procedures before the study. There are no added risks.

Where is the study run from?
Amsterdam UMC (Netherlands)

When is the study starting and how long is it expected to run for?
December 2023 to February 2026

Who is funding the study?
1. Amsterdam UMC (Netherlands)
2. Intuitive Surgical Inc. (USA)
3. Dutch Cancer Society (KWF)

Who is the main contact?
1. Prof. Marc G. Besselink, m.g.besselink@amsterdamumc.nl
2. Prof. Mohammed Abu Hilal, abuhilal9@gmail.com

Contact information

Type(s)
Principal Investigator

Contact name
Prof Marc Besselink

ORCID ID
http://orcid.org/0000-0003-2650-9350

Contact details
De Boelelaan 1117
Amsterdam
Netherlands
1081HV
+31 (0)625126464
m.g.besselink@amsterdamumc.nl

Type(s)
Principal Investigator

Contact name
Prof Mohammad Abu Hilal

ORCID ID
http://orcid.org/0000-0002-3162-4639

Contact details
Via Leonida Bissolati 57
Brescia
Italy
25124
+39 (0)303518028
abuhilal9@gmail.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NL77750.018.21

Study information

Scientific Title
Minimally invasive versus open pancreatoduodenectomy for pancreatic and periampullary neoplasms (DIPLOMA-2): an international multicenter patient-blinded randomized controlled trial; Robotic versus open pancreatoduodenectomy in patients with primary resectable pancreatic head cancer (DIPLOMA-2x2): an international multicenter patient and assessor blinded randomized controlled trial

Acronym
DIPLOMA-2; DIPLOMA-2x2

Study objectives
Current study hypothesis as of 06/02/2025:

The DIPLOMA-2 trial is designed to primarily investigate the safety of minimally invasive pancreatoduodenectomy (MIPD) (both robotic and laparoscopic) in terms of morbidity and mortality, and furthermore to assess if MIPD is superior to open pancreatoduodenectomy (OPD) in terms of time to functional recovery.

The trialists hypothesise that MIPD has similar postoperative morbidity and mortality as compared to OPD, and is superior to OPD in terms of postoperative recovery;

The DIPLOMA-2x2 trial is designed to primarily investigate the oncological safety of robot-assisted pancreatoduodenectomy (RPD) in terms of radicality (R0 resection rate), and furthermore to assess if RPD is superior to open pancreatoduodenectomy (OPD) in terms of time to functional recovery.

The trialists hypothesis that RPD has a similar radicality as compared to OPD, and is superior to OPD in terms of postoperative recovery.

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Previous study hypothesis:

The DIPLOMA-2 trial is designed to primarily investigate the safety of minimally invasive pancreatoduodenectomy (MIPD) (both robotic and laparoscopic) in terms of morbidity and mortality, and furthermore to assess if MIPD is superior to open pancreatoduodenectomy (OPD) in terms of time to functional recovery.

The trialists hypothesise that MIPD has similar postoperative morbidity and mortality as compared to OPD, and is superior to OPD in terms of postoperative recovery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 02/12/2021, Medical Ethics Review Committee of the Academic Medical Center (Meibergdreef 9, 1105 AZ, Amsterdam, Netherlands; +31 (0) 20 5669111; mec@amc.nl), ref: 2021_137
2. Approved 04/10/2021, Comitato Etico di Brescia (Piazzale Spedali Civili 1, 25123, Brescia, Italy; +39 (0)303996507; comitato.etico@asst-spedalicivili.it)
3. Amendment for DIPLOMA-2x2: approved 28/09/2023, Medical Ethics Review Committee of the Academic Medical Center (Meibergdreef 9, 1105 AZ, Amsterdam, Netherlands; +31 (0) 20 5669111; mec@amc.nl), ref: 2021_137

Study design
Multicenter international patient-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Pancreatoduodenectomy for premalignant and malignant disease
For DIPLOMA-2x2: Pancreatoduodenectomy for cancer in the pancreatic head (pancreatic ductal adenocarcinoma [PDAC] and distal cholangiocarcinoma [DCC])

Interventions
Current interventions as of 06/02/2025:

This study is designed for patients with an indication for an elective pancreatoduodenectomy for premalignant and malignant disease. After inclusion, patients are randomly allocated in a 2:1 ratio to either a minimally invasive (MI) procedure or an open procedure, respectively.
Randomization is stratified by:
1. Postoperative fistula risk: normal/high (based on pancreatic duct size and BMI)
2. Pancreatic ductal adenocarcinoma: yes/no
3. Intended MI procedure (in case of randomization to the MI arm): robot-assisted/laparoscopic
Randomization will take place as soon as the surgery can be planned, using Castor EDC, with variable block sizes of 3/6/9. Patients will have a pre-surgery assessment conforming to local protocol.

Patients are blinded for the type of surgery they will receive. Patients will receive a large 40 cm x 40 cm abdominal dressing directly after surgery to mask their treatment (minimally invasive or open) by covering all incisions. This abdominal dressing will be removed when all criteria for functional recovery are met or at postoperative day 5. The dressing can be removed in case of any medical reasons (i.e. wound infection). If earlier inspection is required, attempts are made to maintain patient blinding. This blinding has been proven successful in previous multicenter (European) trials. A complete double-blinding, including medical and nursing ward staff, is considered not feasible. However, a blinded adjudication committee will assess the primary endpoint.

Patients are asked to wear a personal, display-blinded Fitbit™ Inspire 2 device up to 90 days after surgery, that will measure activity. A preoperative baseline activity will be captured.

Patients are asked to complete quality of life questionnaires at baseline, 1 month, 3 months and 6 months after surgery. Survival rates will be calculated for 1 and 3 years postoperative;

The DIPLOMA-2x2 study is designed for patients with an indication for an elective pancreatoduodenectomy for PDAC and DCC. After inclusion, patients are randomly allocated in a 2:1 ratio to either a minimally invasive (MI) procedure or an open procedure, respectively.
Randomization is stratified by:

1. Postoperative fistula risk: normal/high (based on pancreatic duct size and BMI)
2. Pancreatic ductal adenocarcinoma: yes/no
3. Intended MI procedure (in case of randomization to the MI arm): robot-assisted/laparoscopic
Randomization will take place as soon as the surgery can be planned, using Castor EDC, with variable block sizes of 3/6/9. Patients will have a pre-surgery assessment conforming to local protocol.

Patients are blinded for the type of surgery they will receive. Patients will receive a large 40 cm x 40 cm abdominal dressing directly after surgery to mask their treatment (robot-assisted or open) by covering all incisions. This abdominal dressing will be removed when all criteria for functional recovery are met or at postoperative day 5. The dressing can be removed in case of any medical reasons (i.e. wound infection). If earlier inspection is required, attempts are made to maintain patient blinding. This blinding has been proven successful in the previous DIPLOMA-2 trial. A complete double-blinding, including medical and nursing ward staff, is considered not feasible. However, blinded pathologists will assess the primary endpoint.

Patients are asked to complete quality of life questionnaires at baseline, 1 month, 3 months and 6 months after surgery. Survival rates will be calculated for 1, 3, and 5 years postoperatively.

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Previous interventions:

This study is designed for patients with an indication for an elective pancreatoduodenectomy for premalignant and malignant disease. After inclusion, patients are randomly allocated in a 2:1 ratio to either a minimally invasive (MI) procedure or an open procedure, respectively.
Randomization is stratified by:
1. Postoperative fistula risk: normal/high (based on pancreatic duct size and BMI)
2. Pancreatic ductal adenocarcinoma: yes/no
3. Intended MI procedure (in case of randomization to the MI arm): robot-assisted/laparoscopic
Randomization will take place as soon as the surgery can be planned, using Castor EDC, with variable block sizes of 3/6/9. Patients will have a pre-surgery assessment conforming to local protocol.

Patients are blinded for the type of surgery they will receive. Patients will receive a large 40 cm x 40 cm abdominal dressing directly after surgery to mask their treatment (minimally invasive or open) by covering all incisions. This abdominal dressing will be removed when all criteria for functional recovery are met or at postoperative day 5. The dressing can be removed in case of any medical reasons (i.e. wound infection). If earlier inspection is required, attempts are made to maintain patient blinding. This blinding has been proven successful in previous multicenter (European) trials. A complete double-blinding, including medical and nursing ward staff, is considered not feasible. However, a blinded adjudication committee will assess the primary endpoint.

Patients are asked to wear a personal, display-blinded Fitbit™ Inspire 2 device up to 90 days after surgery, that will measure activity. A preoperative baseline activity will be captured.

Patients are asked to complete quality of life questionnaires at baseline, 1 month, 3 months and 6 months after surgery. Survival rates will be calculated for 1 and 3 years postoperative.

Intervention Type
Procedure/Surgery

Primary outcome measure

Current primary outcome measure as of 06/02/2025:

Overall postoperative morbidity and mortality, measured in terms of the comprehensive complication index (CCI), representing the accumulative morbidity up to 90 days after surgery, scored using the Clavien-Dindo classification for complications;

For DIPLOMA-2x2: radicality (R0 resection rate)

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Previous primary outcome measure:

Overall postoperative morbidity and mortality, measured in terms of the comprehensive complication index (CCI), representing the accumulative morbidity up to 90 days after surgery, scored using the Clavien-Dindo classification for complications

Secondary outcome measures

1. Days to functional recovery after surgery, which requires that all the following criteria are met: adequate pain control with oral analgesia only; ability to maintain sufficient (≥50% of required) caloric intake; absence of intravenous fluid administration; restoration of mobility to an independent level (or to preoperative level); no signs of active infection (no fever, decreasing C-reactive protein below 150 mg/L). Measured by the local surgical team every postoperative day until all criteria are reached.
2. Postoperative activity, measured using a personal, display-blinded Fitbit™ Inspire 2 device at baseline (1-2 weeks preoperative) and up to 90 days postoperatively
3. Intraoperative parameters: total operative time (first skin incision to fully closed skin incisions, min); time of reconstruction phase; blood loss; serious intra-operative complications; conversion; reason for conversion; surgeon's mental strain and ergonomics. All variables are collected by the surgical team using an intraoperative electronic case report form (eCRF), completed at the end of surgery.
4. Pancreatic surgery specific complications including pancreatic fistula; delayed gastric emptying; postoperative bleeding; bile leak; chyle leak; other gastrointestinal leakage; wound infection; pneumonia; re-interventions (radiographic, endoscopic, surgical); in hospital, 30- and 90-day mortality. All variables are collected by the local study team using a postoperative eCRF up to 90 days after surgery.
5. Oncological outcomes: R0 resection rate; number of resected lymph nodes / lymph node ratio; start of adjuvant therapy (if indicated); time to adjuvant therapy in days (if indicated). All variables are collected by the local study team using a postoperative eCRF up to 6 months after surgery. Overall and disease-free survival is measured using 1- and 3-year follow-up by the local study team.
6. Hospitalization parameters: days from surgery to discharge (length of hospital stay); readmission rates; total hospitalized days; intensive care admission. . All variables are collected by the local study team using a postoperative eCRF up to 90 days after surgery.
7. Patient-reported outcomes: (health-related) quality of life measured using validated European Organisation for Research and Treatment of Cancer (EORTC) questionnaires (electronic or post-distributed) at baseline, 1, 3, 6 months, 1 and 3 years; patient-reported time to return to pre-operative condition; patient satisfaction with treatment; complications of scar, all collected using validated EORTC questionnaires (electronic or post-distributed) at 6 months.
8. Costs: during the 6 months after randomization, use of hospital healthcare resources is collected from case report forms, and electronic hospital information systems; quality-adjusted

life years (QALY) using the EORTC EQ-5D-5L questionnaire, calculated up to 6 months and 3 years.

Overall study start date
01/07/2020

Completion date
31/12/2026

Eligibility

Key inclusion criteria
Current inclusion criteria as of 06/02/2025:

1. Age at least 18 years
2. Indication for elective pancreatoduodenectomy for a tumor located in the pancreatic head, distal bile duct, duodenum or ampulla of Vater
3. Both minimally invasive pancreatoduodenectomy and open pancreatoduodenectomy are technically feasible for radical resection, according to the local treatment team
4. Pre-operative multiphase CT scan showing no signs of vascular involvement (in case of (suspected) malignancy: maximum 28 days old CT-scan available)
5. Fit to undergo pancreatoduodenectomy according to the surgeon and anesthesiologist
6. Written informed consent

For DIPLOMA-2x2
1. Age at least 18 years
2. Indication for elective pancreatoduodenectomy for cancer in the pancreatic head (PDAC and DCC)
3. Both robot-assisted pancreatoduodenectomy and open pancreatoduodenectomy are technically feasible for radical resection, according to the local treatment team
4. Pre-operative multiphase CT scan showing no signs of vascular involvement (in case of (suspected) malignancy: maximum 28 days old CT-scan available)
5. Fit to undergo pancreatoduodenectomy according to the surgeon and anesthesiologist
6. Written informed consent

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Previous inclusion criteria:

1. Age at least 18 years
2. Indication for elective pancreatoduodenectomy for a tumor located in the pancreatic head, distal bile duct, duodenum or ampulla of Vater
3. Both minimally invasive pancreatoduodenectomy and open pancreatoduodenectomy are technically feasible for radical resection, according to the local treatment team
4. Pre-operative multiphase CT scan showing no signs of vascular involvement (in case of (suspected) malignancy: maximum 28 days old CT-scan available)
5. Fit to undergo pancreatoduodenectomy according to the surgeon and anesthesiologist
6. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
288; For DIPLOMA-2x2: 396 (of which 119 patients yet included in the DIPLOMA-2 trial)

Key exclusion criteria
Current exclusion criteria as of 06/02/2025:

1. A second cancer requiring resection during the same procedure
2. Chronic pancreatitis as indication (including Groove pancreatitis)
3. Any vascular involvement (portal vein, superior mesenteric vein, superior mesenteric artery, coeliac artery or hepatic artery)
4. Pregnancy
5. Body mass index >35 kg/m²
6. Participation in another study with interference of study outcomes

For DIPLOMA-2x2:
1. A second cancer requiring resection during the same procedure
2. Chronic pancreatitis as indication (including Groove pancreatitis) or necrotizing pancreatitis
3. Any vascular involvement (portal vein, superior mesenteric vein, superior mesenteric artery, coeliac artery or hepatic artery)
4. Pregnancy
5. Body mass index >35 kg/m²
6. Participation in another study with interference of study outcomes

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Previous exclusion criteria:

1. A second cancer requiring resection during the same procedure
2. Chronic pancreatitis as indication (including Groove pancreatitis)
3. Any vascular involvement (portal vein, superior mesenteric vein, superior mesenteric artery, coeliac artery or hepatic artery)
4. Pregnancy
5. Body mass index >35 kg/m²
6. Participation in another study with interference of study outcomes

Date of first enrolment
17/01/2022

Date of final enrolment
01/02/2026

Locations

Countries of recruitment
Belgium

France

Germany

Italy

Luxembourg

Netherlands

Russian Federation

Spain

United States of America

Study participating centre
Amsterdam UMC
De Boelelaan 1777
Amsterdam
Netherlands
1081 HV

Study participating centre
Fondazione Poliambulanza Istituto Ospedaliero
Via Leonida Bissolati 57
Brescia
Italy
25124

Study participating centre
Erasmus Medical Center
Rotterdam
Netherlands
-

Study participating centre

Catharina Ziekenhuis
Eindhoven
Netherlands
-

Study participating centre
Medisch Spectrum Twente
Enschede
Netherlands
-

Study participating centre
Leiden University Medical Center
Leiden
Netherlands
-

Study participating centre
UMC Utrecht, st. Antonius / RAKU
Utrecht
Netherlands
-

Study participating centre
AZ Groeninge
Kortrijk
Belgium
-

Study participating centre
Beaujon Hospital
Clichy
France
-

Study participating centre

Centre Hospitalier Universitaire de Reims
Reims
France
-

Study participating centre
Ospedale Niguarda
Milan
Italy
-

Study participating centre
University of Pisa
Pisa
Italy
-

Study participating centre
Ospedale Misericordia
Grosseto
Italy
-

Study participating centre
Centre Hospitalier de Luxembourg
Luxembourg
Luxembourg
-

Study participating centre
Heidelberg University
Heidelberg
Germany
-

Study participating centre

University Hospital Lübeck
Lübeck
Germany
-

Study participating centre
Antwerp University Hospital
Antwerp
Belgium
-

Study participating centre
University of Verona Hospital Trust
Verona
Italy
-

Study participating centre
Hamburg Eppendorf University Hospital
Hamburg
Germany
-

Study participating centre
Azienda Ospedaliero Universitaria Pisana
Pisa
Italy
-

Study participating centre
Linköping University Hospital
Linköping
Sweden
-

Study participating centre

Hospital Universitari Germans Trias I Pujol
Barcelona
Spain
-

Study participating centre
Johns Hopkins Hospital
-
United States of America
-

Sponsor information

Organisation
Amsterdam University Medical Centers

Sponsor details
De Boelelaan 1117
Amsterdam
Netherlands
1081 HV
+31 (0)204444444
secretariaatrvb@amc.nl

Sponsor type
Hospital/treatment centre

Website
https://www.amsterdamumc.org/research/institutes/cancer-center-amsterdam.htm

ROR
https://ror.org/05grdyy37

Organisation
Fondazione Poliambulanza Istituto Ospedaliero

Sponsor details
Via Leonida Bissolati 57
Brescia
Italy
25124
+39 (0)303518028
cge.segreteria@poliambulanza.it

Sponsor type
Hospital/treatment centre

Website
http://www.poliambulanza.it/english-area

ROR
https://ror.org/03kt3v622

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academisch Medisch Centrum

Alternative Name(s)
Academic Medical Center, AMC

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Netherlands

Funder Name
Fondazione Poliambulanza

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Italy

Funder Name
Intuitive Surgical

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
The study protocol and statistical analysis plan will be published before the end of participant inclusion. The results of this study will be submitted to a high-impact peer-reviewed medical journal regardless of the study outcome.

Intention to publish date
01/01/2025

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.5	18/11/2021	11/01/2022	No	Yes
Protocol article		12/10/2023	16/10/2023	Yes	No