

LAELAPS-3

Gepubliceerd: 08-10-2019 Laatste bijgewerkt: 18-08-2022

Learning curve inflection before 50-60 cases

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22238

Bron

NTR

Verkorte titel

LAELAPS-3

Aandoening

Malignancy of the pancreatic head.

Ondersteuning

Primaire sponsor: Amsterdam UMC (AMC)

Overige ondersteuning: M.J.W. Zwart received funding from the board of directors from the Amsterdam UMC (location AMC) for studies on safe implementation of innovative techniques in advanced pancreatic surgery. He also received funding from the Dutch Digestive Foundation, ('Maag Lever Darm Stichting'), for studies on the before mentioned topics (Agreement ID: I 16-05). LAELAPS-3 received an educational grant from Intuitive Surgical® for funding of proctoring travel, suturing material was sponsored by ETHICON, Johnson & Johnson.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Major complications: Clavien/Dindo grade >2

Toelichting onderzoek

Achtergrond van het onderzoek

Background: Safe implementation of robotic pancreatoduodenectomy is essential and may be facilitated by multicenter training programs. Data on multicenter training programs for robotic pancreatoduodenectomy (RPD) are lacking. The aim of this study is to investigate outcomes and learning curves of a multicenter training program for RPD including biotissue drills and the first consecutive patients.

Methods: A multicenter training program in RPD is designed according to the UPMC method, which includes videos, virtual reality (VR) simulation exercises, biotissue drills, online RPD video-bank, and proctoring (March 2016-September 2019). Prospectively collected outcomes are evaluated for the trained centers including all consecutive RPDs performed including 90-day follow-up. Cumulative sum (CUSUM) analysis is performed to assess the learning curve. Operative videos are assessed using an objective structured assessment of technical skill.

Doel van het onderzoek

Learning curve inflection before 50-60 cases

Onderzoeksopzet

None

Onderzoeksproduct en/of interventie

Multicenter robotic pancreatoduodenectomy training program

Contactpersonen

Publiek

Amsterdam UMC
Maurice Zwart

0613330878

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age equal or above 18 years
- Indication for elective pancreatoduodenectomy because of a malignant, pre-malignant or symptomatic benign disease located in the pancreatic head, distal bile duct, duodenum or ampulla of Vater
- The procedure can be performed both laparoscopically and open according to the local surgeon
- Fit to undergo pancreatoduodenectomy according to the surgeon and anaesthetist

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Pregnancy

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland
Status: Werving gestart
(Verwachte) startdatum: 01-01-2017
Aantal proefpersonen: 400
Type: Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies
Datum: 08-10-2019
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8073
Ander register	METC Amsterdam UMC (AMC) : W17_129 # 17.149

Resultaten

Samenvatting resultaten

01-01-2020, 01-01-2022