Added value of 3D-vision during robotic surgery in biotissue pancreatico- and hepaticojejunostomy (LAEBOT 3D2D): a randomized controlled cross-over trial

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25901

Source
Nationaal Trial Register

Brief title
LAEBOT 3D2D

Health condition

Not applicable: Setting is experimental.

Sponsors and support

Primary sponsor: No sponsors.
Source(s) of monetary or material Support: Amsterdam UMC, location AMC

Intervention

Outcome measures

Primary outcome

Primary endpoint will be the time required to complete both PJ and HJ.

Secondary outcome

Secondary endpoint will be the objective structured assessment of technical skill (OSATS; range 12-60) rating; which will be scored by three observers blinded to 3D/2D.

Study description

Background summary

The aim of this study is to determine the added value of 3D-vision, as compared to 2D-vision, when performing PJ and HJ using the da Vinci® robotic system.
Consensus is lacking on the added value of 3D-vision during laparoscopic surgery. Given the improved dexterity with articulating instruments in robotic surgery, the added value of 3D-vision in robotic surgery is unclear.
We will test the added value of 3D-vision on procedure time and surgical performance during robotic biotissue pancreaticojejunostomy (PJ) and hepaticojejunostomy (HJ) as created during robotic pancreatoduodenectomy.
The setting will be experimental.

Study objective

3D-vision during robotic PJ and HJ biotissue anastomoses will reduce procedure time and improve surgical performance as compared to 2D-vision.

Study design

Not applicable.

Intervention

Participants will perform robotic PJ and HJ anastomoses in a biotissue organ model using the da Vinci® system and will be randomized to start with either 3D- or 2D-vision.

Contacts

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Eligibility criteria

Inclusion criteria

Surgeons who are capable of robot-assisted suturing. Experience with minimally invasive pancreatoduodenectomy is not required.

Exclusion criteria

< 18 years
Participants (n = 0) will be excluded if they have no 3D-vision abilities, <200 seconds of arc ((assessed using a Randot Test (Stereo optical, Chicago, IL, USA).

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2017
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	02-10-2019
Application type:	First submission

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
NTR-new	NL8063
Other	METC AMC : W17_066 # 17.084

Study results

Summary results
LAELAPS3Dvs2D
LAELAPS-2