Targeted Abdominal Lymph nodE dissections randomized for surgical NavigaTion (TALENT)

Published: 27-10-2016
Last updated: 31-12-2024

To evaluate if navigation assistance results in more successful localization and removal of extra-regional abdominal lymph nodes compared to standard surgery. Extra regional lymph nodes are defined as suspect target lymph nodes outside the standard...

Ethical review	Approved WMO
Status	Completed
Health condition type	Metastases
Study type	Interventional

Summary

ID

NL-OMON50713

Source
ToetsingOnline

Brief title
Navigated abdominal lymph node dissections

Condition

- Metastases
- Haematological and lymphoid tissue therapeutic procedures

Synonym
Abdominal pathologic lymph nodes

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: NKI-AvL

Intervention

Keyword: Electromagnetic navigation, Lymph node dissections, Rectal cancer, Urologic tumours

Outcome measures

Primary outcome

Primary:

The main study parameter is the percentage of successful procedures, in which

failure is defined as :

Presence of residual target lymph nodes on follow-up imaging

Secondary outcome

Secondary:

• Time to localization and removal of the lymph node

• Overall surgery time

• Number of individual retreived lymph nodes

• Blood loss

• Operator satisfaction

• Health related quality of life (EQ-5D-5L, QLQ-C30, and QLQ-CR29 or QLQ-PR25)

Study description

Background summary

Image-guided navigation surgery allows for full utilization of pre-operative imaging during surgery, and has the potential of reducing both irradical resections and morbidity. In this study we will randomize patients which will undergo an abdominal lymph node dissection in order to evaluate the actual technical and clinical benefit of navigation

Study objective

To evaluate if navigation assistance results in more successful localization and removal of extra-regional abdominal lymph nodes compared to standard surgery. Extra regional lymph nodes are defined as suspect target lymph nodes outside the standard resection area.

Study design

Randomized controlled trial with stratification for surgical specialism (surgery, urology, gynaecology)

Intervention

In the study patients will be randomized between the use of a surgical navigation system or not. The operation itself will be perforemed according to current clinical practice, and the navigation system will be used for better localization and orientation during the procedure.

Study burden and risks

All included patients will undergo one pre-operative planning CT scan with intravenous contrast (10 min). Participation in the study might involve an additional visit to the hospital for the included patients due to challenging CT scheduling. Patients in the experimental arm will also undergo one intra-operative CT scan just before the start of surgery without intravenous contrast (10 min). This will be done with the patient anesthesized, which means an extension of anesthesia by 10 minutes.

Because of the nature of this study we do not expect any adverse events to occur due to the study related procedures. The navigation system is there to enhance the anatomical insight without any negative impact on standard surgery.

Contacts

Public
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
Amsterdam 1066CX
NL
Scientific
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
Amsterdam 1066CX

NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age >= 18
Scheduled for open abdominal surgery
Planned removal of at least 1 extra-regional lymph node suspect on imaging, as assessed by the specialist who will perform the operation
Informed consent

Exclusion criteria

Metal implants in the pelvic area which could influence the 3D modelling or navigation accuracy
Contra-indication for contrast enhanced CT scanning

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	24-01-2017
Enrollment:	82
Type:	Actual

Medical products/devices used

Generic name:	Surgical Navigation
Registration:	No

Ethics review

Approved WMO Date:	27-10-2016
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	26-01-2017
Application type:	Amendment
Review commission:	METC NedMec

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
CCMO	NL58037.031.16

Study results

Date completed: 14-10-2021

Results posted: 30-07-2024

First publication
26-07-2024