Intra-operatieve fluorescente beeldvorming van schildwachtklieren bij maagkanker patiënten

- CANDIDATE NUMBER 15774

- NTR NUMBER NTR4280

- ISRCTN   ISRCTN wordt niet meer aangevraagd.

- DATE ISRCTN CREATED

- DATE ISRCTN REQUESTED

- DATE REGISTERED NTR   27-nov-2013

- SECONDARY IDS   P09.001 METC LUMC

- PUBLIC TITLE   Intra-operatieve fluorescente beeldvorming van schildwachtklieren bij maagkankerpatienten

- SCIENTIFIC TITLE   Intra-operative fluorescent imaging of sentinel lymph nodes in gastric cancer

- ACRONYM   GREEN LIGHT

- HYPOTHESIS   Fluorescent near-infrared imaging can accurately detect lymph nodes non-invasively during SLN mapping in gastric cancer patients.

- HEALT CONDITION(S) OR PROBLEM(S) STUDIED   Bowel cancer

- INCLUSION CRITERIA   gastric cancer patients scheduled for (partial)

gastric resection and lymphadenectomy.

- EXCLUSION CRITERIA   1. History of allergy to iodine, shellfish, indocyanine green or nanocolloid;

2. Pregnancy;

3. Presence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule; those conditions should be discussed with the patient before registration in the trial.

- MEC APPROVAL RECEIVED   yes

- MULTICENTER TRIAL   no

- RANDOMISED no

- GROUP   Parallel

- TYPE   Single arm

- STUDYTYPE   intervention

- PLANNED STARTDATE 1-feb-2013

- PLANNED CLOSINGDATE   1-aug-2014

- TARGET NUMBER OF PARTICIPANTS   20

- INTERVENTIONS   Standard lymphadectomy will be performed. During surgery, the near-infrared dye ICG:Nanocoll will be injected around the tumor and lymphatic pathways and lymph nodes will be visualized non-invasively using our experimental camerasystem.

- PRIMARY OUTCOME   Identification rate, defined as the proportion of patients in whom sentinel and non-sentinel lymph nodes was identified with the fluorescent signal of ICG:Nanocoll.

- SECONDARY OUTCOME   Tumor-to-background ration, accuracy, sensitivity, specificity.

- TIMEPOINTS   The primary and secondary outcomes will be assessed during surgery and pathological assessment.

- TRIAL WEB SITE   N/A

- STATUS   open: patient inclusion

- CONTACT FOR PUBLIC QUERIES   Prof. Dr. C.J.H. Velde, van de

- CONTACT FOR SCIENTIFIC QUERIES   MD PhD A.L. Vahrmeijer

- SPONSOR/INITIATOR   Leiden University Medical Center (LUMC)

- FUNDING

(SOURCE(S) OF MONETARY OR MATERIAL SUPPORT)   Leiden University Medical Center (LUMC)

- PUBLICATIONSN/A

- BRIEF SUMMARY   SLN technique has been used in the management of a variety of cancers to avoid unnecessary lymphadenectomy, and also in gastric cancer several studies support the validity of the SLN concept. Fluorescent imaging using near-infrared probes is an innovative technique to directly visualize lymphatic pathways and lymph nodes. Previous studies already used indocyanine green (ICG) in SLN mapping in gastric cancer and were able to successfully identify SLN with either preoperative submucosal and intraoperative subserosal injections around the tumor. Less false negative cases were found after preoperative submucosal injection. However, also a more widely spread of ICG in the lymphatic vessels with time, which results in the detection of more 2nd-tier nodes. Recent publications showed good retention in the SLN with ICG coupled to a nanocolloid. The aim of the study is to determine the proportion of gastric cancer patients in whom SLNs can be identified non-invasively with fluorescent imaging using ICG coupled to a nanocolloid (ICG:Nanocoll) during standard lymphadenectomy.

- MAIN CHANGES (AUDIT TRAIL)
- RECORD   27-nov-2013 - 6-dec-2013