Sentinel lymph node detection in vulvar cancer.

Gepubliceerd: 31-08-2009 Laatst bijgewerkt: 18-08-2022

Sentinel lymph node detection with fluorescent probes.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28244

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

vulvar cancer
vulvacarcinoom

Ondersteuning

Primaire sponsor: UMCG
Overige ondersteuning: UMCG

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Identification of sentinel lymph nodes within the allocated procedure (usually 15-30 minutes).

Toelichting onderzoek

Achtergrond van het onderzoek

This project consists on the realization followed by the clinical validation of a diagnostic procedure dedicated to the identification and localization of sentinel lymph nodes (SLN) in the case of squamous cell carcinoma of the vulva. An intra-operative near-infrared fluorescence (NIRF) imaging camera and the use of a NIRF optical contrast agent will be evaluated for its feasibility to detect the sentinel lymph node in patients with squamous cell carcinoma of the vulva. The sentinel lymph node technique, based on the propagation of cancer cells in the lymphatic system, allows a better evaluation of tumor staging, prognosis and therapeutic strategy determination. The current golden standard consists of the use of a radiocolloid and a blue dye. This requires an peritumoural intradermal injection on the day prior to surgery. The injection of the optical contrast agent for the use of the NIRF-camera takes place during surgery, under full anaesthesia. The end-goal of this intra-operative imaging procedure, therefore, is to significantly reduce the psychological stress on the patient. Gynecologic oncologists, surgeons and fundamental physics applied to medical imaging researchers are involved in this project.

Doel van het onderzoek

Sentinel lymph node detection with fluorescent probes.

Onderzoeksopzet

Surgery.

Onderzoeksproduct en/of interventie

Patients with unifocal squamous cell carcinoma of the vulva stage I or II, smaller than 4 cm undergoing surgery, combined with a sentinel lymph node procedure, will receive an peritumoural injection with indocyanine green (ICG) prior to surgery, but after administration of full anaesthesia. During the operative procedure NIRF imaging for detection of the SLN (i.e. ICG accumulation) will take place.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Female > 21 years of age;

2. Unifocal squamous cell carcinoma of the vulva proven by histology on a biopsy, depth of invasion > 1mm, tumour size < 4mm, no suspicious inguinal nodes on CT scan or palpation.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Pregnancy;

2. Renal, cardiac or pulmonary failure (ASA III-IV);

3. Previous or present hyperthyreoidism;

4. Iodine allergy or previoius anaphylactic reactions.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-07-2009
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	31-08-2009
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	NL1870
NTR-old	NTR1983
Ander register	UMCG/ CCMO : BICG06UMCG-NIRF/NL26982.042.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A