Validation of USPIO-enhanced MRI for detection of lymph node metastases in head and neck carcinoma: a pilot study.

Published: 11-12-2018
Last updated: 11-04-2024

We would like to develop a method for preparation and preservation of the neck dissection specimen in order to facilitate reliable co-registration with the nano-MR images of the neck.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Metastases
Study type	Observational invasive

Summary

ID

NL-OMON46202

Source
ToetsingOnline

Brief title
USPIO-NECK

Condition

- Metastases

Synonym
head and neck cancer, head and neck carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: head and neck cancer, lymph node metastases, magnetic resonance imaging, ultrasmall superparamagnetic iron oxide particles (USPIO)

Outcome measures

Primary outcome

Sensitivity and specificity of the USPIO-enhanced MRI detecting (subclinical)

lymph node metastases in head-and-neck cancer.

Secondary outcome

Development of a scoring system providing criteria for the radiological

assessment of USPIO-enhanced MR images regarding the assessment of cervical

lymph nodes.

Study description

Background summary

The presence of lymph node metastases has a large impact on prognosis and treatment in head*and neck cancer patients and necessitates treatment intensification. High*resolution imaging techniques such as ultrasound, MRI* and CT*scanning and ultrasound*guided fine needle aspiration (FNA), have resulted in an increasingly improved detection rate of lymph node metastasis. However, despite increased resolution, up to 20% of patients with a pre* operative clinically negative neck will have occult metastases in the neck dissection specimen anno 2017. New, non*invasive techniques are needed to improve the detection of small lymph node metastases. One promising new technique is nano*MRI, an MR*imaging technique in which ultrasmall superparamagnetic iron oxide (USPIO) particles are intravenously infused as a contrast agent in patients 24*36 hours before the MRI examination and has proven to be of value in detecting lymph node metastases. Results on diagnostic accuracy of nano*MRI in head*and*neck cancer are sparse, but promising, with reported sensitivity ranging from 80% to 95% and the specificity from 81 to 100%. Most of these were performed over 10 years ago with older techniques and were small in cohort size. We want to validate this technique in our large population of head*and*neck cancer patients and directly translate our findings

into clinical practice.

Study objective

We would like to develop a method for preparation and preservation of the neck dissection specimen in order to facilitate reliable co-registration with the nano-MR images of the neck.

Study design

Observational study

Study burden and risks

Except for the discomfort of lying in a MRI scanner for about 30-45 minutes, MRI offers no risks for patients without pre-assessed contra-indications. The USPIO contrast agent can cause a contrast reaction during and shortly after administration. Therefore this administration is performed within the hospital under supervision of qualified personnel. Surgical interventions are performed if indicated by the hospital*s current guidelines.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Males and females aged >18 years.
- Patients with histopathologically proven cT0-4N0-2M0 squamous cell carcinoma of the oral cavity, oropharynx, hypopharynx, or unknown primary.
- Patients planned for a neck dissection.
- Patients providing informed consent

Exclusion criteria

- Patients who underwent radio- and/or chemotherapy to the neck before surgery.
- Patients who had a previous lymphadenectomy in the head and neck region.
- Patients who are pregnant and/or breast-feeding.;Patients with contraindications to MRI:
- Epilepsy
- Metallic implants ;Patients with contraindications to ferumoxtran-10:
- prior allergic reaction to ferumoxtran-10 or any other iron preparation
- prior allergic reaction contributed to dextran or other polysaccharide, in any preparation
- prior allergic reaction to contrast media of any type
- hereditary hemochromatosis, thalassemia, sickle cell anemia

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting

Start date (anticipated):	02-05-2019
Enrollment:	25
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Combidex
Generic name:	ultrasmall superparamagnetic iron oxide particles (USPIO)

Ethics review

Approved WMO Date:	11-12-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	12-02-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	02-10-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	16-06-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
EudraCT	EUCTR2018-002168-14-NL
CCMO	NL66248.091.18