ISRCTN44750045 https://doi.org/10.1186/ISRCTN44750045

Sentinel node biopsy in head and neck cancer: development of a new technique

Submission date 04/01/2019	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 06/02/2019	**Overall study status** Completed	
Last Edited 06/02/2019	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Early stage (T1-T2) squamous cell carcinoma of the oral cavity with clinically N0 neck is associated with a false-negative rate of 40% for neck metastasis. As neck metastasis is the main predictive factor in head and neck cancer, it is of paramount importance to stage those patients accurately in order to offer them the best chance of survival. Sentinel lymph node (SLN) biopsy is a minimally invasive procedure which is validated in the evaluation of the presence of occult neck metastasis. We present an original technique, using a small iron oxide nanoparticles (SPIO) dextran coated of 60 nm as a tracer and detected per-operatively with Sentimag. The SPIO offer the additional advantages of being detected in the lymph nodes during the pathologic exam, establishing a positive control in the identification of the correct SLN, and, of being traceable during the magnetic resonance imaging. Last, it is not radioactive, facilitating its use in routine practice.

The primary outcome is the correlation of nodal staging with Sentimag-guided SLNB with the nodal staging by the completion neck dissection.

Who can participate?
Any patient with a new cN0 HNSCC within the oral cavity and oropharynx for which the multi-disciplinary tumor board proposal is surgical treatment.

What does the study involve?
Small iron oxide nanoparticles are injected around the tumor before the patient undergoes tumor resection and a neck dissection. Before doing the neck dissection we identify the sentinel lymphnode percutaneously with a probe called Sentimag. If found, we excise it and send it separately for pathology exam. The rest of the neck dissection is performed as usual. The patient is the woken up and the rest of the recovery and follow-up is as per standards.

What are the possible benefits and risks of participating?
There are no particular benefit for the patient except for the thorough pathological examination of the SLNB with multi level slices. Risks are limited except for side effects of the SPIO (allergy) and the discomfort of the peritumoral injection.

Where is the study run from?
Geneva University Hospital

When is the study starting and how long is it expected to run for?
January 2012 until December 2018

Who is funding the study?
Geneva University Hospital

Who is the main contact?
Dr Nicolas Dulguerov
Nicolas.Dulguerov@hcuge.ch

Contact information

Type(s)
Public

Contact name
Dr Nicolas Dulguerov

ORCID ID
http://orcid.org/0000-0001-8676-3698

Contact details
Dpt of Otorhinolaryngology and Head and Neck surgery
Clinical Neurosciences
4, rue Gabrielle-Perret-Gentil
Geneva
Switzerland
1211 Geneva 14

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CER 13-217

Study information

Scientific Title
Sentimag and MRI interstitial lymphangiography in Head and Neck cancer Sentinel Node Biopsy

Study objectives

Our hypothesis is that Sentinel lymph node can be accurately identified with a small iron oxide particle (SPIO).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical committee for research on human subjects, 07/01/2014, ref. CER:13-217.

Study design
Interventional, non-randomised, single-centre

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Head and Neck cancer

Interventions
The intervention involves injecting a small iron oxide nanoparticles around the tumor. Then, the patient is taken to theater to undergo tumor resection and a neck dissection. Before doing the neck dissection we identify the sentinel lymphnode percutaneously with a probe called Sentimag. If founded, we excise it and send it separately for pathology exam. The rest of the neck dissection is performed as usual. The patient is the woken up and the rest of the recovery and follow-up is as per standards.

Intervention Type
Procedure/Surgery

Primary outcome measure
Correlation of nodal staging with Sentimag® guided SLNB and the nodal staging by the completion neck dissection .

Secondary outcome measures

1. Identification of the SPION tracer in the SLN with pre-operative T2* MRI
2. Per-operative identification of the SLN with Sentimag®-guidance
3. Histopathological detection of the SPION in the SLN and in the remaining nodes within the completion neck dissection.

Overall study start date
01/01/2012

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Diagnosed with a new cN0 HNSCC within the oral cavity and oropharynx
2. Multi-disciplinary tumor board proposal is surgical treatment.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
24

Key exclusion criteria
1. Age below 18 years old at the time of diagnosis
2. Pregnancy
3. Previous Head and Neck cancer
4. Other cancer in the last two years (other than non-melanoma skin cancer)
5. Previous neck radiotherapy
6. Contra-indication to magnetic resonance Imaging (pacemeaker, cerebral metallic implant, claustrophobia)
7. Overload iron disease
8. Allergy to dextran

Date of first enrolment
07/01/2014

Date of final enrolment
04/09/2018

Locations

Countries of recruitment

Switzerland

Study participating centre
Geneva University Hospital
Dpt of Otorhinolaryngology and Head and Neck surgery
Clinical Neurosciences
4, rue Gabrielle-Perret-Gentil
Geneva
Switzerland
1211 Geneva 14

Sponsor information

Organisation
Geneva University Hospital

Sponsor details
Dpt of Otorhinolaryngology and Head and Neck surgery
Clinical Neurosciences
4, rue Gabrielle-Perret-Gentil
Geneva
Switzerland
1211 Geneva 14

Sponsor type
Hospital/treatment centre

Website
https://www.hug-ge.ch/

ROR
https://ror.org/01m1pv723

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Dpt of Otorhinolaryngology and Head and Neck surgery

Results and Publications

Publication and dissemination plan
Results publication 1st trimester 2019

Intention to publish date
01/03/2019

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be included in the subsequent results publication.

IPD sharing plan summary
Other