

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

<b>Submission date</b> 04/01/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 06/02/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 06/02/2019	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## 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 then 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  
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## Contact information

**Type(s)**  
Public

**Contact name**  
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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 (pacemaker, 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