

# Study on lung cancer screening in head and neck cancer patients using low-dose CT and chest x-ray

<b>Submission date</b> 27/10/2024	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 28/10/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/03/2025	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Head and neck cancer patients are at an elevated risk of lung metastasis and secondary primary lung cancer, with a notable incidence rate of 11.7% for second lung cancers. Alarming, 86% of these patients die from secondary lung cancer within 4 months of diagnosis. This study aims to assess whether low-dose CT (LDCT) screening, compared to chest X-ray (CXR), can improve early detection, reduce lung cancer-related deaths, and identify optimal diagnostic procedures in this population.

### Who can participate?

Patients aged 18 years and over with newly diagnosed head and neck cancer

### What does the study involve?

Participants will be randomly assigned to one of two groups: either chest radiography or LDCT for lung cancer surveillance. Initial screening will occur at diagnosis, with annual follow-ups. Both groups will receive the same frequency of screening, with the only difference being the type of imaging. The study will track lung cancer detection rates and the diagnostic tests required to confirm diagnoses.

### What are the possible benefits and risks of participating?

This study offers participants the potential benefit of early lung cancer detection, which may improve survival rates. Radiation exposure is minimal, and all participants will continue to receive standard care.

### Where is the study run from?

Jewish General Hospital (JGH) (Canada)

### When is the study starting and how long is it expected to run for?

July 2015 to December 2023

Who is funding the study?  
Investigator initiated and funded

Who is the main contact?  
Dr Naif Fnais, nfnais@ksu.edu.sa

### **Study website**

<https://www.jgh.ca/care-services/otolaryngology-ent-and-head-and-neck-surgery/>

## **Contact information**

### **Type(s)**

Public, Scientific, Principal Investigator

### **Contact name**

Dr Naif Fnais

### **Contact details**

Pavilion E, Room E-903 (General ENT) and E-904 (Head & Neck Oncology)  
Jewish General Hospital  
3755 Côte-Ste-Catherine Road  
Montreal  
Canada  
H3T 1E2  
+1 (0)514 340 8246  
nfnais@ksu.edu.sa

## **Additional identifiers**

### **EudraCT/CTIS number**

Nil known

### **IRAS number**

### **ClinicalTrials.gov number**

Nil known

### **Secondary identifying numbers**

Nil known

## **Study information**

### **Scientific Title**

Lung Cancer Surveillance for Patients with Head and Neck Cancer (LCS-HNC)

### **Acronym**

LCS-HNC

### **Study objectives**

Does lung cancer screening using low-dose computed tomography vs chest radiography (CXR) confer any survival benefit in patients with head and neck squamous cell cancer (HNSCC) with negative initial staging images?

### **Ethics approval required**

Ethics approval required

### **Ethics approval(s)**

Approved 05/07/2015, Jewish General Hospital Research Ethics Committee (A-925- 3755 Chem. de la Côte-Sainte-Catherine, Montréal, H3T 1E2, Canada; +1 (0)514340 8222 ext 22445; [convenance@jgh.mcgill.ca](mailto:convenance@jgh.mcgill.ca)), ref: CODIM-MBM-15-066

### **Study design**

Randomized parallel study

### **Primary study design**

Interventional

### **Secondary study design**

Randomised parallel trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Screening

### **Participant information sheet**

Not applicable

### **Health condition(s) or problem(s) studied**

Lung metastasis or second primary lung cancer in head and neck cancer patients

### **Interventions**

Participants will be randomly assigned to one of two groups: either chest radiography or low-dose computed tomography (LDCT) for lung cancer surveillance. Initial screening will occur at diagnosis, with annual follow-ups. Both groups will receive the same frequency of screening, with the only difference being the type of imaging. The study will track lung cancer detection rates and the diagnostic tests required to confirm diagnoses.

### **Standard-of-care and ethical considerations:**

This study upholds the standard of care, providing LDCT only in cases where existing evidence supports its use in high-risk populations. Both imaging types are routine practice for these patients, and there are no ethical concerns, as participants have the right to withdraw at any time.

### **Recruitment strategy:**

Eligible participants will be approached by their primary treating physician, with random group assignment handled by a research assistant using a computerized system. The study includes a diverse range of eligible participants, without specific restrictions on vulnerable groups.

**Intervention Type**

Other

**Primary outcome measure**

Sensitivity and specificity of imaging methods (LDCT and CXR) for detecting lung metastases or second primary lung cancer, assessed using imaging analysis confirmed by biopsy in positive cases at baseline and 6- to 12-month follow-ups after treatment

**Secondary outcome measures**

Overall survival and disease-free survival measured using Kaplan-Meier survival analysis at 3 and 5 years

**Overall study start date**

05/07/2015

**Completion date**

31/12/2023

**Eligibility****Key inclusion criteria**

Treatment naïve patients diagnosed with HNSCC undergoing treatment with no prior lung cancer diagnoses or recent abnormal chest computed tomography (CT) findings

**Participant type(s)**

Patient, Employee

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

200

**Total final enrolment**

137

**Key exclusion criteria**

Patients with HNSCC aged 55 to 74 years with a smoking history of at least 30 pack-years, and who were currently smoking or had quit within during the past 15 years

**Date of first enrolment**

01/09/2015

**Date of final enrolment**

31/12/2022

## Locations

### Countries of recruitment

Canada

### Study participating centre

#### Jewish General Hospital

3755 Chem. de la Côte-Sainte-Catherine

Montreal

Canada

H3T 1E2

## Sponsor information

### Organisation

Jewish General Hospital

### Sponsor details

3755 Côte-Ste-Catherine Road

Montreal

Canada

H3T 1E2

+1 (0)514 340 8222, ext 25387

convenance@jgh.mcgill.ca

### Sponsor type

Hospital/treatment centre

### Website

<https://www.jgh.ca/care-services/otolaryngology-ent-and-head-and-neck-surgery/>

### ROR

<https://ror.org/056jjra10>

## Funder(s)

### Funder type

Other

### Funder Name

Investigator initiated and funded

## Results and Publications

### Publication and dissemination plan

Planned publication in a peer-reviewed journal

### Intention to publish date

21/11/2024

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Dr Naif Fnais (nfnais@ksu.edu.sa). All patient data will be securely stored, coded, and protected. Identifiers will be removed from computerized data to ensure anonymity, with data accessible only to the principal and co-investigators. Upon completion, data will be archived securely, following confidentiality protocols.

Type of data: demographic, clinical, and imaging data.

Dates of availability: available post-publication of primary study findings, expected 21/11/2024.

Consent obtained: written informed consent was obtained from all participants.

Ethical or legal restrictions: data access is restricted to researchers with IRB approval to ensure confidentiality.

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		06/03/2025	12/03/2025	Yes	No