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

Submission date
27/10/2024

Recruitment status
No longer recruiting

Registration date
28/10/2024

Overall study status
Completed

Last Edited
12/03/2025

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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. Alarmingly, 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

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Naif Fnais

Contact details
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Additional identifiers

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), ref: CODIM-MBM-15-066

Primary study design
Interventional

Study design
Randomized parallel study

Study type(s)
Screening

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(s)
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

Key secondary outcome(s)
Overall survival and disease-free survival measured using Kaplan-Meier survival analysis at 3 and 5 years

Completion date
31/12/2023

Eligibility

Key inclusion criteria
Treatment naïïve 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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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

ROR
https://ror.org/056jjra10

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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?
Results article		06/03/2025	12/03/2025	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes