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Cancer diagnostics using artificial intelligence

Submission date	Recruitment status	[_] Prospectively registered
13/09/2022	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
16/09/2022	Completed	[X] Results
Last Edited	**Condition category**	[X] Individual participant data
13/03/2025	Cancer	

Plain English summary of protocol

Background and study aims
The exact location, size and activity level of malignant tumors in the head and neck region can be difficult to determine accurately. A correct assessment these tumors on PET-CT images is essential in order to secure successful treatment. The aim of this study is to investigate whether or not artificial intelligence tools can assist in the assessment of head and neck tumors.

Who can participate?
Patients of all ages who were treated for head and neck cancer with radiotherapy at Rigshospitalet between 01/01/2014 and 01/01/2020, who were also scanned with PET-CT for treatment planning purposes

What does the study involve?
The study does not have an effect on patient treatment. Tumor delineations are used to train and validate artificial intelligence algorithms in order to determine if the quality of these is sufficient to be used in a clinical setting.

What are the possible benefits and risks of participating?
Participation involves no risks or benefits.

Where is the study run from?
Rigshospitalet (Denmark)

When is the study starting and how long is it expected to run for?
January 2020 to June 2022

Who is funding the study?
1. Louis-Hansen Fonden (Denmark)
2. Capital Region of Denmark (Denmark)
3. Hartmann Fonden (Denmark)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
480_21

Study information

Scientific Title
Clinical comparison and validation of openly available deep learning methods for automated metabolic tumor volume delineation on PET-CT of head and neck cancer

Study objectives
Artificial intelligence can be used for automated tumor delineation of head and neck cancer in quality matching that of a nuclear medicine specialist.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/06/2020, Danish Patient Safety Authority (Islands Brygge 67, 2300 København S, Denmark; +45 (0)7228 6600; stps@stps.dk), case no. 31-1521-340, ref: SMMO.

Study design
Single-centre observational study

Primary study design
Observational

Secondary study design

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not applicable

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

Interventions
A single-centre study of automated tumor delineation accuracy with retrospectively registered head and neck cancer patients scanned with PET-CT for radiotherapy treatment planning between 01/01/2014 and 01/01/2020. Patients are not exposed to any new interventions as a part of this study. The researchers study PET-CT scans that were acquired as a part of routine clinical radiotherapy treatment.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Automated metabolic tumor volume delineation

Primary outcome measure
Tumor delineation accuracy measured using the dice coefficient at a single timepoint

Secondary outcome measures
1. Tumor delineation accuracy measured using Hausdorff distance at a single timepoint
2. Lesion-level detection accuracy measured using f1 score (harmonic mean of positive predictive value and sensitivity) at a single timepoint

Overall study start date
01/01/2020

Completion date
06/06/2022

Eligibility

Key inclusion criteria
Patients treated with radiotherapy for cancer of the head and neck who received a PET-CT scan for treatment planning purposes as a part of clinical routine

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
1200. 260 for testing and as many as possible for training. The sample size for testing was determined based on power considerations. For training, the researchers needed as many cases as possible.

Total final enrolment
1184

Key exclusion criteria
1. Patient PET or CT image not acquired according to required protocol
2. Clinical metabolic tumor volume delineation incomplete

Date of first enrolment
21/03/2021

Date of final enrolment
15/10/2021

Locations

Countries of recruitment

Denmark

Study participating centre
Rigshospitalet
Blegdamsvej 9
Copenhagen
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Sponsor information

Organisation
Rigshospitalet

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Sponsor type
Hospital/treatment centre

Website
https://www.rigshospitalet.dk/afdelinger-og-klinikker/diagnostisk/klinisk-fysiologi-og-nuklearmedicin/Sider/default.aspx

ROR
https://ror.org/03mchdq19

Funder(s)

Funder type
Charity

Funder Name
Aage og Johanne Louis-Hansens Fond

Alternative Name(s)

Aage and Johanne Louis-Hansen's Foundation, Aage og Johanne Louis-Hansen ApS, Louis-Hansen Fonden, Aage and Johanne Louis-Hansen Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Denmark

Funder Name
Region Hovedstaden

Alternative Name(s)
Capital Region of Denmark

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Denmark

Funder Name
Hartmann Fonden

Alternative Name(s)
Hartmann Foundation, Brødrene Hartmanns Fond

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Denmark

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/08/2023

Individual participant data (IPD) sharing plan
The researchers intend to publish the datasets generated and analysed at either https://www.cancerimagingarchive.net/ or using an in-house server. The data sharing is pending legal approval, and the platform used for sharing depends on this approval. The type of data shared will be PET images, CT images and tumor volumes delineated by nuclear medicine physicians. The data is expected to become available indefinitely for researchers upon publication at the end of 2022. The data will be accessible upon legal approval for healthcare researchers in an anonymized form without prior participant consent.

Updated 13/03/2025:
The data is shared and available at the website https://rigshospitalet-tumour-segmentation.regionh.dk/-

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 11	16/09/2021	16/09/2022	No	No
Statistical Analysis Plan	version 1		16/09/2022	No	No
Results article		22/02/2024	23/02/2024	Yes	No
Dataset			13/03/2025	No	No