

Cancer diagnostics using artificial intelligence

Submission date 13/09/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 16/09/2022	Overall study status Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 13/03/2025	Condition category Cancer	<input checked="" type="checkbox"/> Individual participant data

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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Contact information

Type(s)

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Diagnostic

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

Denmark

2100

Sponsor information

Organisation

Rigshospitalet

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, The Hartmann Foundation, The Hartmann Brothers 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

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?
Results article	Participant information sheet	22/02/2024	23/02/2024	Yes	No
Dataset			13/03/2025	No	No
Participant information sheet		11/11/2025	11/11/2025	No	Yes
Protocol file	version 11	16/09/2021	16/09/2022	No	No
Statistical Analysis Plan	version 1		16/09/2022	No	No