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Evaluation of an artificial intelligence tool to automate radiotherapy treatment

Submission date 30/06/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 22/09/2022	**Overall study status** Ongoing	
Last Edited 17/07/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
The aim of this study is to look at whether an Artificial Intelligence (AI) based computer program can automate two components of the radiotherapy treatment pathway to a sufficient quality standard to enable its routine clinical use. The two components include the delineation (outlining) of anatomical areas that are at risk of tumour spread and at risk of radiation damage, and the definition of the position, size and shape of the radiation beams.
AI-based computer programs have been developed to perform tasks that would normally require direct human involvement by oncologists and medical physicists. Proposed advantages include improved treatment accuracy, as well as a reduction in the time (from weeks to minutes) and human resources needed to deliver radiotherapy, which this study will test.

Who can participate?
Patients aged 18 years and over with a new diagnosis of head and neck cancers, cervical cancer or prostate cancer that will be treated with radiotherapy.

What does the study involve?
The researchers will use the images from radiotherapy planning CT scan for the study. Following consent for the study, no further information is required from patients.

What are the possible benefits and risks of participating?
There are no expected risks as participants will be treated according to the standard treatment plan with no additional tests or treatment required. There is no immediate benefit for participants in this study as they will be treated according to the current standard. It is hoped that the information from this study will help to improve treatment for future patients with cancer.

Where is the study run from?
MRC CTU at UCL (UK)

When is the study starting and how long is it expected to run for?
June 2021 to September 2026

Who is funding the study?
1. National Institutes of Health (NIH) (USA)
2. Rising Tide Foundation for Clinical Cancer Research (Switzerland)

Who is the main contact?
Dr Ajay Aggarwal, mrcctu.archery@ucl.ac.uk

Contact information

Type(s)
Principal investigator

Contact name
Dr Ajay Aggarwal

Contact details
MRC CTU at UCL
90 High Holborn
London
United Kingdom
WC1V 6LJ
+44 (0)20 7670 4700
mrcctu.archery@ucl.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
NCT05653063

Protocol serial number
AI01

Study information

Scientific Title
ARCHERY - A prospective observational study of artificial intelligence based radiotherapy treatment planning for cervical, head and neck, and prostate cancer

Acronym
ARCHERY

Study objectives
Current study hypothesis as of 22/05/2024:
AI can automate target volume contouring and produce radiotherapy plans that are able to meet international standards for treatment quality

Previous study hypothesis:
AI can automate target volume delineation and produce radiotherapy plans that are able to meet international standards for treatment quality

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/04/2023, University College London Research Ethics Committee (Research Ethics Team, Office of the Vice-Provost (Research), University College London, 2 Taviton Street, London, WC1H 0BT, United Kingdom; N/A; ethics@ucl.ac.uk), ref: 24627.001

Study design
Prospective observational cohort study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cervical, head and neck, and prostate cancer

Interventions
A web-based artificial intelligence (AI) auto-planning tool

The CT scan taken at the time of treatment planning is uploaded to a web server called the Radiotherapy planning assistant which automates the contouring of target organs and areas of high-risk disease as well as defining the size, shape and number of radiotherapy beams to treat the cancer. The final plan is downloaded to the local treatment planning system where the doses are recalculated and clinical peer review is undertaken before the plan can be used clinically.

In this study patients will not be treated with the AI tool but the manual plan created by the local teams. As the participants will not be receiving the intervention, there will be no follow-up for participants.

Intervention Type
Other

Primary outcome(s)
Current primary outcome measure as of 17/07/2025:

Overall acceptability of the automated treatment plan. This is a composite outcome including both the assessment of the delineated clinical target volumes (CTVs) and organs-at-risk (OARs) with reference to internationally accepted contouring guidelines and the adherence to pre-defined dosimetric constraints for each tumour type. Timepoint: clinical peer review.

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Previous primary outcome measure:

Overall acceptability of the automated treatment plan. This is a composite outcome including both the assessment of the delineated clinical target volumes (CTVs) and organs-at-risk (OARs) using a pre-defined scale and the adherence to acceptable dosimetric constraints for each tumour type. Timepoint: clinical peer review.

Key secondary outcome(s))
1. Time and resource savings measured during manual and automated processes:
1.1. Date/time CT planning scan performed
1.2. Date/time of delineation started/completed (grade and number of staff members)
1.3. Date/time of radiotherapy treatment planning completed (grade and number of staff members involved)
1.4. Date/time CT (with gross tumor volume [GTV] contoured manually) sent for autcontouring and planning
1.5. Date/time autocontouring and planning completed
2. Cost-effectiveness measured using time-driven activity-based costing tool based on timing and resource use inputs
Timepoint: clinical peer review

Completion date
01/09/2026

Eligibility

Key inclusion criteria
Current inclusion criteria as of 17/07/2025:

1. Patients with:
1.1. Histologically confirmed head and neck cancers of the oropharynx, larynx, hypopharynx, and nasopharynx (American Joint Committee on Cancer [AJCC] Stage I-IVB) that have given consent for radical radiotherapy (with or without concurrent chemotherapy). Patients can be included if they have had induction chemotherapy prior to radiotherapy
OR
1.2. Histologically confirmed primary cervical cancer (International Federation of Gynaecology and Obstetrics [FIGO]/AJCC Stage IB-IIIC1) that have given consent for radical radiotherapy (with or without concurrent chemotherapy). Patients can be included if they have had induction chemotherapy prior to radiotherapy.
OR
1.3. Histologically confirmed primary prostate cancer (AJCC Stage I-IIIC) that have given consent for radical radiotherapy. Patients can be included if they have had prior chemotherapy or are taking a hormonal therapy for their prostate cancer.
2. Provide signed informed consent to participate in the study
3. Aged ≥18 years

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Previous inclusion criteria as of 22/05/2024:

1. Patients with:
1.1. Histologically confirmed head and neck cancers of the oropharynx, larynx, hypopharynx, and nasopharynx (American Joint Committee on Cancer [AJCC] Stage I-IVB) that have given consent

for radical radiotherapy. Patients can be included if they have had induction chemotherapy prior to radiotherapy
OR
1.2. Histologically confirmed primary cervical cancer (International Federation of Gynaecology and Obstetrics [FIGO]/AJCC Stage IB-IIIC1) that have given consent for radical radiotherapy
OR
1.3. Histologically confirmed primary prostate cancer (AJCC Stage I-IIIC) that have given consent for radical radiotherapy
2. Provide signed informed consent to participate in the study
3. Aged ≥18 years

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Previous inclusion criteria:

1. Consecutive patients at each participating centre with histologically confirmed head and neck cancers of the oropharynx, larynx, hypopharynx and nasopharynx (Stage I-III) that have given consent for primary curative radiotherapy
2. Consecutive histologically confirmed primary cervical cancer patients (Stage IB-IIIB including pelvic node positive) that have given consent for radical radiotherapy
3. Patients aged over 18 years
4. Written informed consent to participate in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Current exclusion criteria as of 17/07/2025:

1. Patients requiring radiotherapy after curative surgery or surgery that is intended to remove as much of the tumour as possible
2. Patients receiving a palliative dose of radiotherapy
3. Patients that have any metal implants within the treatment field e.g. hip prostheses. Dental implants are acceptable.

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Previous exclusion criteria as of 22/05/2024:

1. Patients requiring radiotherapy after curative surgery or surgery that is intended to remove as much of the tumour as possible
2. Patients receiving palliative radiotherapy

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Previous exclusion criteria:

1. Patients requiring radiotherapy after curative or de-bulking surgery

Date of first enrolment
27/12/2023

Date of final enrolment
01/12/2025

Locations

Countries of recruitment
India

Jordan

Malaysia

South Africa

Study participating centre
University of Malaya Medical Center
Lembah Pantai
Kuala Lumpur
Malaysia
59100

Study participating centre
King Hussein Cancer Center
Queen Rania St 202
Amman
Jordan
11733

Study participating centre
Tygerberg Academic Hospital, Stellenbosch University
6 Jan Celliers Rd
Stellenbosch Central

Stellenbosch
South Africa
7600

Study participating centre
Groote Schuur Hospital, University of Cape Town
Main Rd
Observatory
Cape Town
South Africa
7935

Study participating centre
Tata Memorial Hospital
Parel East
Parel
Mumbai
India
400012

Study participating centre
Tata Medical Center
14, MAR(E-W)
DH Block (Newtown)
Action Area I
Newtown
Kolkata
India
700160

Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
National Institutes of Health

Alternative Name(s)
US National Institutes of Health, Institutos Nacionales de la Salud, NIH, USNIH

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Funder Name
Rising Tide Foundation for Clinical Cancer Research

Alternative Name(s)
RTFCCR

Funding Body Type
Private sector organisation

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

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Ajay Aggarwal (mrcctu.archery@ucl.ac.uk).

Data will be shared according to the MRC CTU and UCL's controlled access approach, based on the following principles:
1. No data should be released that would compromise an ongoing trial or study.
2. There must be a strong scientific or other legitimate rationale for the data to be used for the requested purpose.
3. Investigators who have invested time and effort into developing a trial or study should have a

period of exclusivity in which to pursue their aims with the data, before key trial data are made available to other researchers.
4. The resources required to process requests should not be under-estimated, particularly successful requests which lead to preparing data for release. Therefore adequate resources must be available in order to comply in a timely manner or at all, and the scientific aims of the study must justify the use of such resources.
5. Data exchange complies with Information Governance and Data Security Policies in all of the relevant countries.

Applications for data can be made at any time and will be considered on a case-by-case basis. Researchers wishing to access ARCHERY data should contact the Trial Management Group in the first instance. Following approval of a request, a formal agreement will be drawn up between the relevant parties prior to the release of any data, and measures will be put in place to ensure that ethical and regulatory requirements relating to data confidentiality are upheld.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes