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A study testing a more precise type of radiotherapy for cancer to reduce pain or discomfort

Submission date 14/11/2025	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 18/11/2025	**Overall study status** Ongoing	
Last Edited 17/11/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
This study aims to compare the pain scores of patients receiving conventional radiotherapy and spatially fractionated lattice radiotherapy (SFRT).
About half of all cancer patients will undergo palliative radiotherapy (RT) during their illness to manage distressing symptoms such as pain and bleeding. Great and more durable pain responses have been observed with higher dose RT, including stereotactic body radiation therapy (SBRT). Unfortunately, it is not possible to treat large tumors with SBRT for several reasons. SFRT is an innovative RT technique that addresses some of the limitations of SBRT. SFRT uses very high doses of radiation on specific spots inside the tumour, creating a lattice-like pattern. The outer edges of the tumor get a much lower dose, which helps protect nearby healthy organs from radiation. Early phase studies have shown excellent response rates in terms of pain as well as dramatic and rapid resolution of large tumours. Similar results with high responses and low toxicity have been reported in the setting of locally advanced and bulky lung cancer, head and neck cancer, and cervical cancer.

Who can participate?
Patients aged 18 years and over diagnosed with solid tumour and requiring radiation to a lesion greater than 5 cm

What does the study involve?
Once enrolled in the study, the patients will be randomly allocated to one of two treatments: conventional radiotherapy or lattice radiotherapy. All patients will receive their dose in five fractions. At baseline, post-treatment and 1, 3, and 6 months follow-up visits, they will be asked about their pain level and which pain medication they are taking.

What are the possible benefits and risks of participating?
The benefits of participating may be that patients may have an improved pain response. However, it is not certain at the moment. The risks of participating are very similar to the risks of

a person receiving conventional radiotherapy. This can include symptoms in correlation to the treatment area. Radiotherapy has a risk of tumor lysis syndrome (TLS), which may be elevated with lattice radiotherapy.

Where is the study run from?
Princess Margaret Cancer Centre (Canada)

When is the study starting and how long is it expected to run for?
November 2025 to January 2028

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Jelena Lukovic, jelena.lukovic@uhn.ca

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
24-6019

Study information

Scientific Title
Lattice Radiation Therapy versus Conventional Radiation Therapy for the Palliation of Large Tumors

Acronym
LATTICE-PAL

Study objectives

Primary objective: determine if treatment with spatially fractionated radiation therapy (LRT) leads to a greater proportion of patients achieving a complete response in pain/discomfort at 30 days, measured with the international consensus pain response (ICPR), compared with standard conventional RT.

Secondary objectives:
1. Pain response pattern at 1,3, and 6 months: complete, partial, stable or progressive pain
2. Re-irradiation rate within the 6-month follow-up period
3. Incidence of treatment-related toxicity rates > Grade 2
4. Imaging-based tumor response rates at 3 and 6 months post treatment
5. Local control, progression-free survival (PFS) and overall survival (OS)

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 16/10/2025, University Health Network Research Ethics Board (700 University Ave. 4th Floor, Toronto, M5G 1Z5, Canada; +1 (0)416 581 7849; reb@uhnresearch.ca), ref: 24-6019

Study design
Phase III single-site two-arm interventional randomized trial

Primary study design
Interventional

Study type(s)
Efficacy, Quality of life, Treatment

Health condition(s) or problem(s) studied
Solid tumour

Interventions
Lattice Radiation Therapy: Spatially fractionated radiation therapy, via LATTICE Radiotherapy (LRT) in five fractions to discrete sub-volumes within a tumor

Once enrolled in the study, the patients will be randomly allocated using REDCap to one of two treatments: conventional radiotherapy or lattice radiotherapy. All patients will receive their dose in five fractions. At baseline, post-treatment and 1, 3, and 6 months follow-up visits, they will be asked about their pain level and which pain medication they are taking.

Intervention Type
Device

Phase
Phase III

Drug/device/biological/vaccine name(s)
Lattice radiation therapy and conventional radiation therapy

Primary outcome(s)

Pain is measured using international consensus for pain response (ICPR) at baseline and 30 +/-7 days following treatment

Key secondary outcome(s))
1. Pain response pattern measured using ICPRE at 1, 3, and 6 months post RT
2. Reirradiation rate is measured by counting the number of patients receiving reirradiation within 6 months following radiotherapy
3. Treatment-related toxicity is measured using Common Terminology Criteria for Adverse Events (CTCAE) v5 at baseline, after treatment, and at 1, 3 and 6 months after treatment
4. Objective tumour response is measured using RECIST with the CT scans at baseline and at 3 and 6 months post-treatment
5. Overall survival and progression-free survival measured from randomization to progression at any site or death
6. Quality of life is measured using the EORTC-QLQ C30 questionnaire at baseline, after radiation treatment, and at 1, 3, and 6 months post-treatment

Completion date
01/01/2028

Eligibility

Key inclusion criteria
1. Diagnosis of solid tumor by at least one criterion below:
1.1. Pathologically or cytologically proven solid tumor greater than 5 cm (largest dimension) from a primary site or site of metastasis and unsuitable for surgical resection or definitive RT
1.2. HCC diagnosed by standard imaging criteria permitted: arterial enhancement and delayed washout on multiphasic computerized tomography (CT) or magnetic resonance imaging (MRI) in the setting of cirrhosis or chronic hepatitis B or C without cirrhosis
2. Eastern Cooperative Oncology Group (ECOG) Status: 0-4 within 14 days of randomization
3. In the investigator’s opinion, patient requires palliative radiation therapy to a lesion >5 cm measured in one of the following ways:
3.1. Imaging performed within 90 days prior to randomization per Response Evaluation Criteria in Solid Tumors (RECIST)
3.2. CT simulation performed for radiation planning
4. Able to understand and provide written consent
5. Willing and have the ability to complete the baseline and post-treatment questionnaires (short form brief-pain inventory) and to maintain a pain diary
6. Patient is not pregnant, planning on becoming pregnant or planning on fathering a child in the next 90 days
7. Patient must be accessible for treatment and follow-up. Investigators must ensure the patients randomized on this trial will be available for complete documentation of the treatment, adverse events, and follow-up

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Mixed

Lower age limit
18 years

Upper age limit
99 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Prior radiotherapy that would result in substantial overlap of the irradiated volume thus precluding per protocol treatment
2. Requirement for urgent surgical intervention prior to radiation treatment
3. Confirmed pregnancy
4. Hematologic primary malignancy
5. Medical condition precluding the delivery of per protocol treatment (e.g. connective tissue disorder)
6. Tumors overlying critical CNS, heart or spinal cord compression

Date of first enrolment
19/11/2025

Date of final enrolment
01/07/2027

Locations

Countries of recruitment
Canada

Study participating centre
Princess Margaret Cancer Centre
610 University Avenue
Toronto
Canada
M5G 2C4

Sponsor information

Organisation

University Health Network

ROR
https://ror.org/042xt5161

Funder(s)

Funder type
Not defined

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available