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Tongue-preserving treatment using brachytherapy and intensity-modulated radiation therapy technique for localized tongue cancer

Submission date
10/04/2026

Recruitment status
Recruiting

Registration date
13/04/2026

Overall study status
Ongoing

Last Edited
13/04/2026

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Surgery is usually the standard treatment for early and some locally advanced tongue squamous cell carcinoma (TSCC). However, using an organ-preserving approach that includes interstitial brachytherapy (IBT) can control the cancer just as effectively. Using external beam radiotherapy (EBRT) alone for oral tongue cancer has generally produced poor results. Outcomes improve when EBRT is combined with interstitial brachytherapy and, in some cases, neck surgery, achieving results similar to surgery alone. This is likely because it is difficult for EBRT alone to reliably deliver a high enough radiation dose to the tongue, as the tongue moves and its position changes daily. Surgical cancer control depends on removing enough tissue to achieve clear margins, but speech and swallowing outcomes depend on how much tongue remains. For larger tumours, or those involving the floor of the mouth, IBT offers a way to preserve the tongue while still maintaining good cancer control and function. Most previous studies used EBRT followed by brachytherapy, and many patients then required additional neck surgery for persistent disease. More recent studies show that EBRT can provide reasonable long-term control of disease in the neck, even without planned neck surgery. IBT provides excellent local control of the tongue tumour, with very high control rates reported in early to moderately advanced disease. Combining IBT for the tongue with EBRT for the neck offers a balanced approach: strong local tumour control while also treating regional lymph nodes, often without the need for neck surgery. Because of practical challenges with delivering brachytherapy after EBRT, our centre adopted a reversed approach: delivering brachytherapy first, followed by modern IMRT, with or without chemotherapy, from January 2019 onwards. The initial results from the first eleven patients treated with this approach were presented at an international radiation oncology meeting in 2023. Most of these early patients were alive, free of cancer, and had good speech and swallowing function at one year, suggesting this approach is promising. To our knowledge, this is the first study to formally describe this treatment sequence, known as hybrid brachytherapy followed by adaptive IMRT (HyBIRT). This study of patients treated with the HyBIRT technique will collect detailed information on treatment delivery, side effects, tumour control, survival, and quality of life at regular time points. The results will be compared

with previously published surgical outcomes to assess whether HyBIRT can be a suitable alternative for selected patients. The aim of this study is to assess cancer control, side effects, treatment accuracy, and quality of life in patients treated with HyBIRT and to compare these results with historical surgical data.

Who can participate?
Patients aged 18 years and over with biopsy-proven TSCC affecting the front two-thirds of the tongue

What does the study involve?
Participants will receive HyBIRT treatment, which has two main stages. First, internal radiotherapy (brachytherapy) delivers a focused radiation dose directly to the tongue tumour over five treatment sessions. This is followed by highly precise external radiotherapy (IMRT) to the tongue and neck, tailored to the individual patient. During this phase, most patients also receive weekly chemotherapy, following standard hospital practice.

What are the possible benefits and risks of participating?
This treatment may control the cancer as effectively as surgery, while helping to preserve tongue function and quality of life. The approach aims to treat the cancer effectively while avoiding the long-term speech and swallowing problems that may follow tongue surgery. Risks include short-term and long-term side effects from radiotherapy and chemotherapy. A rare but serious long-term risk is damage to the jawbone caused by radiation. More common side effects include mouth soreness, swallowing difficulties, dry mouth, and tissue stiffness, most of which improve over time. Patients will be closely monitored so that any side effects can be identified and treated early.

Where is the study run from?
Pusat Kanser Tun Abdullah Ahmad Badawi (PKTAAB), Universiti Sains Malaysia

When is the study starting and how long is it expected to run for?
October 2021 to December 2030

Who is funding the study?
Universiti Sains Malaysia

Who is the main contact?
Associate Professor Dr Gokula Kumar Appalanaido, gokula@usm.my , gokudroid@gmail.com

Contact information

Type(s)
Principal investigator, Scientific, Public

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Additional identifiers

Study information

Scientific Title
Hybrid brachytherapy followed by intensity-modulated radiation therapy (HyBIRT) technique for the definitive management of localized tongue cancer

Acronym
HyBIRT Technique

Study objectives
General:
To report on the local control rate, the local regional control rate, toxicities associated with the treatment, overall survival, the radiotherapy technique and radiotherapy/brachytherapy details such as overall treatment time, dose, dose painting methods and also the fusion of external beam radiotherapy and brachytherapy.

Specific:
1. To report on the local control rate of the HyBIRT technique
2. To report on the local regional control rate of the HyBIRT technique
3. To report on toxicities and quality of life associated with the HyBIRT technique
4. To report on the overall survival of patients undergoing the HyBIRT technique
5. To describe the radiotherapy technique of HyBIRT, which combines brachytherapy and external beam radiotherapy
6. To identify factors that could have contributed to good outcomes such as overall treatment time of radiotherapy

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 11/10/2021, Jawatankuasa Etika Penyelidikan (Manusia), JEPeM Universiti Sains Malaysia Human Research Ethics Committee USM (HREC) (Jawatankuasa Etika Penyelidikan (Manusia) JEPeM Universiti Sains Malaysia 11800 Pulau Pinang, Penang, 11800, Malaysia; +60 (0) 9-767 2354; jepem@usm.my), ref: USM/JEPeM/21080564

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Tongue squamous cell cancer (TSCC)

Interventions
The HyBIRT technique involves:
1. Upfront interstitial brachytherapy to tongue tumor 20 Gy in 5F
2. Adoptive intensity modulated radiation therapy (IMRT) to the tongue and neck (56.1 Gy - 69.96 Gy in 33F with dose painting method) with concurrent weekly cisplatin chemotherapy

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Complete resolution of tongue cancer at the primary tongue site and in the neck measured using radiological assessment at 3, 6, 12, 24, 36, 48 and 60 months

Key secondary outcome(s)

Completion date
10/12/2030

Eligibility

Key inclusion criteria
1. Patients with histology-confirmed TSCC
2. Tumor limited to anterior 2/3 (mobile tongue), TNM7 stage T1-4a, N1-2c, M0
3. Refused surgery or unfit for surgery
4. Eastern Cooperative Oncology Group (ECOG) Performance Status 0-2

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit

18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Tumor involving the posterior third of the tongue
2. Radiologically confirmed metastatic disease (M1)
3. Contraindication for nasal intubation
4. ECOG Performance Status 3-4

Date of first enrolment
11/10/2021

Date of final enrolment
31/12/2027

Locations

Countries of recruitment
Malaysia

Study participating centre
Universiti Sains Malaysia
Pusat Kanser Tun Abdullah Ahmad Badawi, Bertam
Kepala Batas
Malaysia
13200

Sponsor information

Organisation
Universiti Sains Malaysia

ROR
https://ror.org/02rgb2k63

Funder(s)

Funder type

Funder Name
Universiti Sains Malaysia

Alternative Name(s)
University of Science, Malaysia, Universiti Sains Malaysia (USM), Universiti Sains Malaysia | George Town, Malaysia | USM, usmofficial1969, University Sains Malaysia (USM), University Sains Malaysia, Science University of Malaysia, USM

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Malaysia

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available