Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Understanding Compliance, disease control, Survival Rates and Complications in Patients following Hypofractionated Postoperative Radiation Therapy (HYPORT) for Head and Neck Squamous Cell Carcinoma instead of conventional treatment

Protocol summary

Study aim

Shortening the overall radiationtherapy(RT) treatment time has advantages in cost and treatment burden, but data on hypofractionated RT in head and neck squamous cell carcinoma are limited. This study assessed the safety of moderately hypofractionated RTin the postoperative setting

Design

This clinical trial study comparing a hypofractionation group and a group with conventional treatment during the years 1403 to 1405 is carried out in the Radio Oncology Department of the Cancer Institute affiliated to Tehran University of Medical Sciences. Patients with a pathologically proven stage I-IVB squamous cell carcinoma of the oral cavity, oropharynx, hypopharynx, and larynx after surgery with pathology showing one or more intermediate risk factors are eligible. Phase 2 was used on 60 patients with control with non-randomized parallel groups

Settings and conduct

This clinical trial study comparing a hypofractionation group and a group with conventional treatment during the years 1403 to 1405 is carried out in the Radio Oncology Department of the Cancer Institute affiliated to Tehran University of Medical Sciences. Patients with a pathologically proven stage I-IVB squamous cell carcinoma of the oral cavity, oropharynx, hypopharynx, and larynx after surgery with pathology showing one or more intermediate risk factors are eligible.

Participants/Inclusion and exclusion criteria

T3/T4 Close margin <5mm Positive LVI/PNI Positive lynph node

Intervention groups

Hypofractional versus conventional

Main outcome variables

Determining treatment tolerance (completion of treatment within 3 weeks) in HNSCC patients undergoing hypofractionated radiotherapy after surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240831062918N1**
Registration date: **2024-09-14, 1403/06/24**
Registration timing: **registered_while_recruiting**

Last update: **2024-09-14, 1403/06/24**
Update count: **0**

Registration date

2024-09-14, 1403/06/24

Registrant information

Name

Elham Mansourabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8825 0625

Email address

elham.mansourabadi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-08-26, 1403/06/05

Expected recruitment end date

2026-08-27, 1405/06/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Understanding Compliance, disease control, Survival Rates and Complications in Patients following Hypofractionated Postoperative Radiation Therapy (HYPORT) for Head and Neck Squamous Cell Carcinoma instead of conventional treatment

Public title

Hypofractionated Radiation Therapy (HYPORT) for Head and Neck Squamous Cell Carcinoma

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

T3/T4 Close margin <5mm Positive LVI/PNI Positive lynph node

Exclusion criteria:

Past radiation Thrapy Metastatic disease feeding tube dependent positive margine ENE

Age

No age limit

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Imam Khomeini Hospital Cancer Institute

City

tehran

Province

Tehran

Postal code

5555555555

Approval date

2024-08-26, 1403/06/05

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1403.222

Health conditions studied

1

Description of health condition studied

HEAD AND NECK SCC

ICD-10 code

C00-D48

ICD-10 code description

HEAD AND NECK SCC

Primary outcomes

1

Description

Treatment tolerance

Timepoint

Determination of LC, DFS and OS for 2,3 and 5 years

Method of measurement

OBSERVATION

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: hypofraction : 46.5 GY/ 15F. IN 5 DAYS/WEEK (3.1 GY per Fraction)

Category

Treatment - Devices

2

Description

Control group: Conventional : 70gy / 35F, with 5Days/Week, (2GY per Fraction)

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Cancer Institute

Full name of responsible person

Reza Ghaletaki
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Sponsors / Funding sources

1

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Tehran University of Medical Sciences
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Part of data
When the data will become available and for how long
3 years from 1406
To whom data/document is available
every body
Under which criteria data/document could be used
No Limitation
From where data/document is obtainable
Imam Khomeini Hospital Cancer Institute
What processes are involved for a request to access data/document
E-Mail
Comments