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Radiotherapy in thyroid carcinoma

Submission date 04/01/2018	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 12/01/2018	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 12/01/2018	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Background and study aims
Differentiated thyroid carcinoma (DTC) (also known as thyroid cancer) is commonly known to recur in patients with advance cases. The aim of this study is to find out how effective is external beam radiotherapy of the neck region in patients with locally advanced thyroid carcinoma for prevention of locoregional recurrence of disease.

Who can participate?
Adults aged 18 and older who were treated with radiotherapy for thyroid carcinoma.

What does the study involve?
Participants with DTC who had external beam radiotherapy of the neck and mediastinum as part of multimodal treatment of locally advanced tumor from year 1973 to 2015 have their medical notes reviewed for information about the control rate and survival.

What are the possible benefits and risks of participating?
There are no benefits or risks with participating in this study.

Where is the study run from?
Institute of Oncology Ljubljana (Slovenia)

When is the study starting and how long is it expected to run for?
June 2010 to January 2018

Who is funding the study?
Slovenian Research Agency (AARS) (Slovenia)

Who is the main contact?
Professor Nikola Besic (Scientific)
nbesic@onko-i.si

Contact information

Type(s)
Scientific

Contact name
Prof Nikola Besic

ORCID ID
https://orcid.org/0000-0002-9874-8767

Contact details
Institute of Oncology
Zaloska 2
Ljubljana
Slovenia
1000
+286 15879518
nbesic@onko-i.si

Additional identifiers

Protocol serial number
OI-RTX-DTC

Study information

Scientific Title
Locoregional Disease Control after External Beam Radiotherapy in Patients with Differentiated Thyroid Carcinoma and pT4 Tumor Stage

Acronym
LC EBRT DTC

Study objectives
Our aim was to find out the rate of locoregional control of the disease after external beam radiotherapy (EBRT) of the neck and mediastinum in patients with DTC and pT4 tumor.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Protocol Review Board Ethics Committee of the Institute of Oncology, 18/11/2010, ref: KSOPKR /18/11/10

Study design
Retrospective single-centre observational study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Differentiated thyroid carcinoma - pT4 tumor stage

Interventions
All 91 patients included in this report had EBRT to the neck and superior mediastinum. Six patients were treated preoperatively with EBRT, four of them with concomitant chemotherapy and two with EBRT only. Even 63 (69%) of our patents were irradiated using antero-posterior opposed fields in supine position with extended neck. The target volume extended from mastoid tips cranially to tracheal bifurcation caudally and to the coracoids laterally, to cover neck lymph nodes regions I-VI, thyroid bed and superior mediastinal lymph nodes. The two beams, using Cobalt unit or 6 MV photon beams, were weighted anteriorily; dose from the anterior field was 1.2 Gray (Gy) and from posterior field 0.6 Gy per fraction, 5 fractions per week. The apices of the lungs were shielded; after the received dose of 39.6 Gy. The spinal cord was also shielded from the posterior field, so the dose to the spinal cord was kept bellow 45 Gy. The prescribed dose to the midplane in vast majority of postoperative patients was 50.4 Gy. A boost dose of 6 - 16 Gy with 1.8 - 2 Gy per fraction was delivered to some patients with macroscopic remnant of disease using photon beams or electron beams avoiding spinal cord. Eight patients were irradiated by 3D technique (TD 50.4-70 Gy, median 63.5 Gy) and 20 patients by intensity-modulated radiotherapy (IMRT) technique (TD 56-70 Gy, median 64 Gy) to the whole neck and mediastinum, while only one patient had only thyroid bed irradiation. The five of six patients treated with EBRT before surgery received 36 Gy before surgery and 14 Gy after surgery, while one patient treated with EBRT before surgery received 50 Gy with IMRT technique.

Patients medical notes are reviewed to take information about locoregional recurrence, cause specific survival and overall survival.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Locoregional control rate was calculated by reviewing patient charts at five and ten years after external beam radiotherapy.

Key secondary outcome(s))
1. Cause-specific survival was calculated using survival curves from patient charts at five and ten years after initial therapy
2. Overall survival was calculated using survival curves from patient charts at five and ten years after initial therapy

Completion date
04/01/2018

Eligibility

Key inclusion criteria
1. Differentiated thyroid carcinoma -pT4 tumor stage
2. Males or females older than 18 years of age

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Younger than 18 years of age.

Date of first enrolment
01/01/2013

Date of final enrolment
13/12/2015

Locations

Countries of recruitment
Slovenia

Study participating centre
Institute of Oncology Ljubljana
Ljubljana
Slovenia
1000

Sponsor information

Organisation
Institute of Oncology

ROR
https://ror.org/00y5zsg21

Funder(s)

Funder type

Government

Funder Name
Slovenian Research Agency (AARS)

Results and Publications

Individual participant data (IPD) sharing plan
We will not provide a dataset because it is in Slovenian language. The dataset will be held in archives of the Research Department of the Institute of Oncology Ljubljana.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes