Protocol No: 31944/24.08.2026

Protocol Date: 24/08/2026

PATIENT INFORMATION SHEET FOR PARTICIPATION IN THE RESEARCH STUDY

Stromal Desmoplastic reaction as a predictive factor for lymph node metastasis in medullary thyroid cancer

Medullary thyroid cancer is a rare but aggressive subtype of thyroid cancer, counting for 5-10% of thyroid cancers with a 1-2% incidence in nodular thyroid diseases. The aggressiveness of this tumor has been correlated with certain factors in the international literature. These are the tumor size, carcinoembryonic antigen (CEA) and calcitonin levels pre- and postoperatively, patient age and sex, TNM stage, type of surgery and time interval to relapse. Recently, desmoplastic stromal reaction is considered a major risk factor for nodal metastases, but is still a debatable topic in the literature(1–6). Our study aims to assess desmoplastic stromal reaction as an independent risk factor for lymph node metastasis in medullary thyroid cancer. This is a prospective multicenter study enrolling patients from Greece and Italy.

The aim of this study is to evaluate stromal desmoplastic reaction as an independent risk factor for nodal metastasis in medullary thyroid cancer. Information regarding desmoplasia will be collected postoperatively and this will not interfere with your therapeutic decisions for the patients. Therapeutic strategy will **NOT** be altered and patients will receive the treatment of choice regarding their disease stage according to the international guidelines.

Confidentiality and Data Protection

All personal data will be treated as **STRICTLY CONFIDENTIAL**. However, individual data may require verification by representatives of health authorities, the hospital's scientific committee, or an independent ethics committee for data monitoring and auditing purposes. Additionally, findings from this study will be used in scientific publications regarding the study results.

Your participation in this study is entirely voluntary. You retain the right to access all personal data entered into the database at any time. Furthermore, you reserve the right to withdraw your consent regarding the inclusion of your data in this study at any point.

Should you have any questions regarding this study, we remain at your disposal to provide clarifications.

INFORMED CONSENT FORM FOR THE PATIENT (OR LEGAL REPRESENTATIVE)

I hereby consent to participate in the study entitled " **Stromal Desmoplastic reaction as a predictive factor for lymph node metastasis in medullary thyroid cancer**".

I understand that my participation is voluntary and that I reserve the right to withdraw from the study at any given time. I have read the information regarding the study, and all of my questions have been answered satisfactorily. I agree that pseudonymized data collected for this study (excluding my name) may be forwarded for evaluation, storage, and electronic processing. I acknowledge that I will receive a signed copy of this consent form, as well as the patient information sheet.

I have been informed and hereby grant permission for my clinical records to be inspected by the Hospital's Scientific Committee, an Independent Ethics Committee, and relevant health authorities.

Name:
.....

(Patient or Legal Representative)

Signature: ..... Date:
.....

(Patient or Legal Representative)

STATEMENT OF THE PERSON OBTAINING INFORMED CONSENT

I hereby certify that the patient has been fully informed regarding the nature, purpose, and implications of this study. The patient information sheet was thoroughly discussed with the patient and provided alongside this informed consent form.

Name:
.....

Signature: ..... Date:
.....