Quality of Life After Interventional Thyroid Treatment (DSR)

Study Identifier NCT03880578

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Study Protocol

Objectives. Aim of the study is to evaluate the quality of life (QoL) in patients with subclinical hyperthyroidism undergoing interventional thyroid treatment, particularly radioiodine treatment (RIT), compared to a control group of euthyroid subjects.

Design. Study design is monocentric, prospective and controlled, comparing two groups of patients, Group 1 comprised of consecutive patients with subclinical hyperthyroidism referred to our department for interventional treatment and Group 2, serving as a control, euthyroid patients presenting at fixed intervals for surveillance of non-toxic nodular goitre. For the intervention, randomised allocation and blinding are not possible, and necessity of intervention is determined independently of the study. The original design included a surgical group with similar characteristics to the RIT group. Due to early problems with the follow-up of surgically treated patients, a decision has been made to conduct the study with two groups only.

Eligibility criteria are adult women or men, aged 18 to 80 years, without any comorbidity or drug use that could potentially interfere with their thyroid function tests and QoL measures. Children and older patients are excluded. Further exclusion criteria are the presence or suspicion of low-T3 syndrome, pregnancy and an inability or unwillingness to provide informed consent. The study aims to recruit 50 patients per group, based on a power analysis conducted prior to the study.

Diagnosis and treatment modality are confirmed and determined prior to and independently of the study.

Study visits were scheduled at baseline. i.e. prior to the intervention in group 1), and 6 months and possibly 12 months thereafter.

The pre-specified primary study end point is a change in the composite score of the ThyPRO quality of life questionnaire between the control group and RIT group before and after intervention. Secondary endpoints include subcategories of the QoL responses, hormonal changes, thyroid structural parameters, thyroid volume, and their relationship with QoL measures.

Methods. QoL was measured with the internationally validated thyroid-specific quality of life questionnaire ThyPro (German version). Thyroid hormones FT3, FT4 and TSH were measured by routine laboratory methods. Thyroid volume was estimated by ultrasonography of the thyroid gland.

Statistical analysis plan. Change over time between groups is assessed with a repeated-measures mixed-effects model. Fixed effects include group (intervention vs control), visit (time point), and the interaction of visit and group (group by visit), the random effect is the subject level. In dealing with missing visits missingness at random (MAR) is assumed. Mean adjusted differences (MAD) between groups over time are reported, based on the interaction term group by visit in the mixed model. A two-sided p value of <0.05 is considered indicative of statistical significance. All analyses are performed in the R statistical programming environment.

Informed Consent

Written informed consent is obtained from each study participant. The protocol has been approved by the Ethics Committee of the University of Duesseldorf, Germany (No. 2018-278-KFogU) and preregistered. The consent form is available upon request in German (original) and English translation.

Funding

The study is investigator initiated. No funding or sponsoring has been received.

Declaration of interest

There is no conflict of interest to report.