

Summary

1. Effects on the thyroid

The effects on the thyroid were surprising. We anticipated that thyroid function will quickly pick up with the application of sufficient doses of TSH. This was not the case. TSH was biologically active as reflected by the increase in serum Tg levels. However, the Tg stimulation was only in the minority of patients reflected by a comparable normalization of fT4 and fT3. Thyroid volume and intrathyroidal blood flow similarly was not altered. These surprising results suggest that the thyroid when not challenged by TSH needs more time for synthesis and release of thyroid hormones than at least anticipated by us. We therefore believe that in a follow-up study at least 3-4 months of treatment are necessary to evaluate the normalization of thyroid physiology in central hypothyroidism. Potentially, thyroid histopathology needs to be assessed by adequate histopathology.

2. Effects on body weight

We anticipated that TSH may have direct action on body fat and bone turn-over. Currently, the measurement of biochemical parameters is not finalized. Thus, early potentially subtle effects are possible. It is not expected from the design of the present study to see stringent general effects on body vs. lean body mass. The lack of any edema together with the lack of any other side effects was however reassuring and suggests that the current protocol to stimulate patients with central hypothyroidism with rec hTSH is safe.

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