Low-Level Laser Therapy in Chronic Autoimmune Thyroiditis
This study has been completed.

First Received on May 14, 2010. Last Updated on May 21, 2010  History of Changes

<table>
<thead>
<tr>
<th>Sponsor:</th>
<th>University of Sao Paulo General Hospital</th>
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</table>
| Collaborators: | Fundação de Amparo à Pesquisa do Estado de São Paulo  
Conselho Nacional de Desenvolvimento Científico e Tecnológico  
Coordenação de Aperfeiçoamento de Pessoal de Nível Superior. |
| Information provided by: | University of Sao Paulo General Hospital |
| ClinicalTrials.gov Identifier: | NCT01129492 |

Purpose
The purpose of this study is to evaluate whether low-level Laser therapy is effective in ameliorating the thyroid function of patients with hypothyroidism caused by chronic autoimmune thyroiditis.
Study Type: Interventional

Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: Low-Level Laser Therapy in Chronic Autoimmune Thyroiditis: Randomized, Placebo Controlled Clinical Trial

Resource links provided by NLM:
MedlinePlus related topics: Thyroid Diseases Ultrasound
U.S. FDA Resources

Further study details as provided by University of Sao Paulo General Hospital:

Primary Outcome Measures:

- The main outcome measure was to gauge the effectiveness of applying LLLT in patients with hypothyroidism caused by CAT evaluated by a significant reduction of the levothyroxine (LT4) mean dose (µ/day) 9 months post-LT4 withdrawal.

[ Time Frame: LT4 dose, concentrations of T3, T4, free T4 and TSH were evaluated and compared before intervention and 9 months post-LT4 withdrawal. ] [ Designated as safety issue: Yes ]

All patients enrolled in the study were undergoing LT4 treatment. They received 10 applications of LLLT or placebo. Thirty days after intervention, LT4 was discontinued in all patients and, if required, reintroduced. T3, T4, free T4 and TSH levels (all laboratory personnel was blinded), were assessed pre-LLLT and then 1, 2, 3, 6 and 9 months post-LT4 withdrawal. The LT4 mean dose pre-LLLT and 9 months post-LT4 withdrawal was compared both in face of normal levels of T3, T4, free T4 and TSH to evaluate LLLT effectiveness.
Secondary Outcome Measures:

- Evaluate the LLLT efficacy in reducing thyroid autoantibodies concentrations. [Time Frame: Thyroid autoantibodies were determined and compared pre-intervention and 9 months post-LT4 withdrawal. ] [Designated as safety issue: Yes]

  Thyroid peroxidase (TPOAb) and thyroglobulin (TgAb) autoantibodies were both determined prior to LLLT and in the 1st, 2nd, 3rd, 6th and 9th months after LT4 withdrawal. All laboratory personnel was blinded to treatment assignment throughout the study.

- Evaluate the LLLT efficacy by quantitative and qualitative ultrasonography parameters. [Time Frame: The ultrasonography parameters observed pre-LLLT were compared with those observed 30 days post-LLLT. ] [Designated as safety issue: Yes]

  B-mode sonography (volume, texture and echogenicity using computerized histogram) as well as power Doppler (vascularization) and pulsed Doppler (maximal systolic peak velocity and resistance index for the thyroid arteries) were performed and compared pre- and 30 days post-intervention by only one experienced and blind investigator, during the use of the same doses of LT4.

Enrollment: 43
Study Start Date: March 2006
Study Completion Date: March 2009
Primary Completion Date: March 2009 (Final data collection date for primary outcome measure)

<table>
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<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
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<tbody>
<tr>
<td>Placebo Comparator: Sham Laser Ten applications of placebo were performed (twice a week) with the same</td>
<td>Device: Low-level Laser therapy A continuous wave (CW) diode laser device (830nm, infrared) with a beam area</td>
</tr>
</tbody>
</table>
method and Laser equipment, which has a placebo function available with a red ordinary light indistinguishable of the Laser light.

<table>
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<tr>
<th>Active Comparator: Active Laser</th>
<th>Device: Low-level Laser therapy</th>
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</thead>
<tbody>
<tr>
<td>Ten applications of low-level Laser therapy (twice a week) were performed with a continuous wave diode laser device (830nm, beam area of 0.2827cm²), using the punctual method, continuous emission mode, output power of 50mW and fluence of 70J/cm².</td>
<td>A continuous wave (CW) diode laser device (830nm, infrared) with a beam area of 0.2827cm² and using the punctual method, continuous emission mode, output power of 50mW and fluence of 70J/cm² (40 seconds at the point of application).</td>
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</table>

Other Names:
- Low intensity Laser therapy
- Low power Laser therapy

**Detailed Description:**
Chronic autoimmune thyroiditis (CAT) is the most common cause of hypothyroidism in iodine-replete areas. An autoimmune dysfunction causes humoral and cellular responses that lead progressively to thyroiditis. There is no effective therapy available that can change the natural history of CAT, which presents a high incidence of hypothyroidism and requires continuous treatment with levothyroxine (LT4).

Laser light can be valuable since the local and systemic actions of low-level laser therapy (LLLT) have been shown to be effective in treating autoimmune diseases, such as rheumatoid arthritis and Sjogren's syndrome. There is also evidence suggesting that LLLT can facilitate regeneration of various tissues and, in animal thyroids, can lead to improvement in microcirculation and increases in serum triiodothyronine (T3) and thyroxine (T4) levels. Since the LLLT is a non-invasive, cost-effective and painless procedure, the objective of this randomized clinical trial was to evaluate the effectiveness of LLLT in patients with hypothyroidism caused by chronic autoimmune thyroiditis, based on patients' thyroid function, their concentration of thyroid autoantibodies, and the parameters of their ultrasonography study.

**Eligibility**

- **Ages Eligible for Study:** 20 Years to 60 Years
- **Genders Eligible for Study:** Both
- **Accepts Healthy Volunteers:** No
Inclusion Criteria:

- Patients previously diagnosed with hypothyroidism induced by chronic autoimmune thyroiditis (CAT). The presence of hypothyroidism, laboratory measurements and ultrasonography criteria were applied to diagnose CAT.
- Significantly elevated concentrations of thyroid peroxidase (TPOAb) and/or thyroglobulin (TgAb) autoantibodies
- Ultrasonography results consistent with CAT
- Patients undergoing LT4 treatment
- Normal (or almost normal) levels of triiodothyronine (T3), thyroxine (T4), free T4 and thyrotropin (TSH)

Exclusion Criteria:

- Use of immunosuppressants, immunostimulants, or other drugs that could interfere with the production, metabolism and transport of thyroid hormones
- CAT with normal thyroid function
- CAT with subclinical hypothyroidism
- Thyroid nodules
- Hypothyroidism stemming from post-partum thyroiditis (up to 18 months after gestation)
- History of Graves' disease
- Thyrotropin receptor antibody (TRAb) detectable
- Prior treatment with radioiodine
- Tracheal stenosis
- Pregnancy
- History of ionizing irradiation and/or neoplasia in the cervical area
- Previous surgical intervention in the thyroid
- Thyroid hypoplasia
- Ectopic thyroid
- Serious illness (cancer, ischemic coronary artery disease, stroke, kidney or liver failure, etc.)

▶ Contacts and Locations
Please refer to this study by its ClinicalTrials.gov identifier: NCT01129492

Locations

Brazil
Sponsors and Collaborators
University of Sao Paulo General Hospital
Fundação de Amparo à Pesquisa do Estado de São Paulo
Conselho Nacional de Desenvolvimento Científico e Tecnológico
Coordenação de Aperfeiçoamento de Pessoal de Nível Superior.

Investigators
Principal Investigator: Danilo B Höfling, Dr. University of São Paulo General Hospital

More Information
No publications provided

Responsible Party: Danilo Bianchini Höfling, University of São Paulo General Hospital - Radiology Department

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Other Study ID Numbers: CAPPesq 375/05
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Keywords provided by University of Sao Paulo General Hospital:
Autoimmune Thyroiditis, Laser, Therapy, Thyroid, Ultrasound

Additional relevant MeSH terms:
- Thyroiditis
- Hashimoto Disease
- Thyroiditis, Autoimmune
- Thyroid Diseases
- Endocrine System Diseases
- Autoimmune Diseases
- Immune System Diseases

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