



British Thyroid Foundation – Cardiff University T3 Safety Study Cardiovascular morbidity and mortality in Liothyronine-treated patients: a linked record cohort study

Patient Information/opt out notice to be advertised on the websites of the British Thyroid Foundation and Thyroid UK

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What is the study about?

Thyroxine is the usual treatment for people with an underactive thyroid problem. Most patients who take thyroxine feel well on this. However, a small proportion of patients do not feel well on thyroxine alone and some practitioners treat such patients with another drug called T3. Whether T3 works just as well as thyroxine remains to be proven and opinions are divided on this. However, a growing number of patients are prescribed T3, mostly from non-conventional or independent medical practices. This is worrying because the long-term safety of T3 has not been established and current guidelines written by medical professionals do not advocate its routine use in practice.

What is the aim of the study?

The current study proposes to investigate whether patients who receive T3 have a greater long-term risk of heart problems, strokes, and death when compared to those who are treated in the standard way with thyroxine.

Why is the study necessary?

Our study will be of importance to patients with thyroid disease. An increasing number of patients are asking for a trial of T3 or natural desiccated thyroid extract (e.g., Armour thyroid) therapy and attending private clinics, but the risks to patients of heart disease, strokes, and death with this practice are unknown. If there is a significantly increased risk, then patients need to be made aware of the facts. On the other hand, if the risk is not different from patients taking thyroxine, then it will allow us to undertake further trials to try and understand if T3 could benefit patients with an underactive thyroid problem.

How will the study be conducted?

We plan to carry out this investigation using data from the private clinic records of the late Dr Gordon Skinner comprising the details of over 4,000 patients treated over a

period of 20 years. Dr Skinner owned a private clinical practice in Birmingham where he treated patients with thyroid problems. Since Dr Skinner's death in 2013, the Vaccine Research Trust that he established has been the Custodian of the clinic data. For this study, administrators of the Vaccine Research Trust will securely transfer patient data containing NHS number and date of birth to the NHS data centre, NHS Digital. NHS digital will then link this data to hospital admissions and death registration data. After linkage, NHS Digital will anonymise the data by removing the NHS number and changing the date of birth to year of birth. The anonymised data will then be forwarded to the Secure Anonymised Information Linkage (SAIL) Databank in Wales.

SAIL is a record of routinely collected health data that is linked to Welsh health and social care records including general practice consultations, hospital admissions, and death records. SAIL will provide anonymised hospital admission and death information data for individuals that have only received thyroxine as well as individuals without thyroid disease at all. The data from patients who were treated with T3, thyroxine, or no thyroid treatment at all will then be made available to researchers at Cardiff University for analysis. This data linkage approach has been designed so that the participants' identity is unknown to researchers or data handlers in SAIL and the researchers at Cardiff University will at no time receive identifiable information regarding the patients involved.

Who is conducting the study?

The study is being conducted by researchers at Cardiff University. The Chief Investigator is Professor Colin Dayan.

Who is funding the study?

The study is funded by the British Thyroid Foundation.

Who has reviewed the study?

The research has been given a favourable ethical opinion by the Wales Research Ethics Committee (Wales REC 1), and is sponsored by Cardiff University, and funded by the British Thyroid Foundation.

How will patients' confidentiality be respected?

We will be able to do this study using a data linkage approach that allows us to conduct the research without knowing the identities of any of the patients or any identifiable health records going outside of the Vaccine Research Trust.

What of patients who do not want their data to be used for this study?

Patients who attended Dr Skinner's clinic and do not want their data to be used for the research can opt out of the study. However, the research team cannot identify patients and cannot directly remove patients' records. Patients have the right to tell NHS Digital if they do not want their information to be used beyond the purpose of providing healthcare. This is known as a 'patient objection'. Please visit NHS Digital's website for further details: <https://www.nhs.uk/your-nhs-data-matters/manage-your-choice>.

Alternatively, you can contact NHS Digital by phone: Telephone number, 0300 303 5678, Monday to Friday, 9am to 5pm (excluding bank holidays). In addition, if you wish for your data to be excluded from only this particular study, you can directly contact the data protection officer of the Vaccine Research Trust by e-mailing info@vaccineresearchtrust.com to request that your data be removed from the study. Alternatively, you can contact the Vaccine Research Trust by post: 22 Alcester Road, Moseley, Birmingham B14 7NR.