

Thyrotoxicosis Study

Recruitment and randomisation - step-by step

Before recruiting patients to this study it is important that local ethical approval and R+D registration are in place, as well as a participating site agreement. Information about how to apply can be found in 'BSPED Clinical Trials - Getting Started Guide' from the Clinical Trials Unit at the University of Cambridge Department of Paediatrics (email sks28@medschl.cam.ac.uk)

1) Entering patients to the study

The protocol outlines the eligibility criteria for entering children into this study:

Inclusion criteria :

All patients with auto-antibody mediated thyrotoxicosis (aged 2-16 years) are eligible for inclusion.

Exclusion criteria :

1. Known toxic adenoma / toxic hyperplasia (germline activating TSHR mutation)
2. Previous episodes of thyrotoxicosis

Patients seen in clinic and identified as eligible may be approached and the study discussed with them. Templates for patient information leaflet will be sent to you by the co-ordinator of the trial (contact details can be found on the CTU web pages). Leaflets can either be printed on headed paper or have local Trust stickers and contact information applied to them. Consent forms also need to be printed on **local headed paper** or have stickers applied to them.

Gaining consents

The patient and his/her family should be given time (at least 24 hours) to think about whether or not they wish to participate in the study.

When taking consent it is important that the information about the study is clearly explained to the patient and his/her family members. The forms should be signed by the patient, his/her carer and the researcher/ person taking consent. A **signed** copy of the consent form should be given to patient, One copy should be retained by the researcher/person taking the consent and one copy should be held in the hospital notes.

It is also important that an **ALERT Sheet** is also completed and held in the notes (this is notification that the patient is involved in a trial).

Contact your TRUST or local R+D office to check what is required.

Once consent has been obtained, a Baseline and Randomisation form should be completed (A **Word** file of **Clinic Forms** will also be provided by the project co-ordinator).

2) Commencing treatment

At diagnosis all patients can be commenced on carbimazole 0.75mg/kg. Some patients may also initially require beta-blockade.

Baseline bloods should be taken and imaging (ultrasound \pm isotope study) should be arranged. Bloods for central analysis should be taken at Visit 1 or Visit 2.

3) Study Randomisation

The Baseline form should be faxed to the CTU (Fax **01223 336 996** marked 'FAO Mark Wilson'). The patient will be randomised to one of two treatment arms: 'Block and Replace' regimen or 'Dose Titration' regimen.

The CTU will allocate the patient a **unique study number** and will either fax or email details of this and the **treatment arm** to which the patient has been randomised.

The patient's **study number** should be **added** to their **consent forms** and a copy of the consent form should be photocopied **with the names of the patient and his/her parent blocked out**. This copy should then be posted/faxed to the data manager at the CTU to be held with the study records. **Completed visit forms** should have the patient's study ID number added to them and **copies** of them should be posted or faxed to the CTU where the data will be added to the study database.

Send forms to: Mark Wilson, University of Cambridge Department of Paediatrics, Box 116 Level 8, Addenbrooke's NHS Foundation Trust, Hills Road, Cambridge, CB2 0QQ.
Fax: 01223 336 996

Consents for genetic studies

Copies of consents for genetic studies with study numbers added should be sent with the blood samples to Dr Tim Cheetham, Chief Investigator, Children's Outpatients, Royal Victoria Infirmary, Queen Victoria Road, Newcastle upon Tyne, NE1 4LP.

Follow up

Treatment protocols as per randomised treatment will be followed for 36 months and then stopped.

Patients will be reviewed off treatment at 3 monthly intervals for the final year (Yr 4) of the study.