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Well being of patients with thyrotoxicosis after radioactive iodine treatment using block and replace compared to titrated regime

Submission date	Recruitment status	[ ] Prospectively registered
29/09/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/09/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/09/2015	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Ponnusamy Saravanan

Contact details
Royal Devon & Exeter Hospital (Wonford)
Barrack Road
Exeter
United Kingdom
EX2 5DW

Additional identifiers

Protocol serial number
N0203173366

Study information

Scientific Title
Well being of patients with thyrotoxicosis after radioactive iodine treatment using block and replace compared to titrated regime

Study objectives
To assess whether the quality of life and well-being at 6 weeks, 6 months & 12 months using SF36-II and GHQ-12 (General Health Questionnaire) after radioactive iodine treatment for thyrotoxicosis is better with block & replacement regime compared to traditional titrating regime.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Radioactive iodine

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Nutritional, Metabolic, Endocrine: Hyperthyroidism

Interventions
All the patients identified as suitable for radioactive iodine treatment will be referred to the endocrine specialist nurse as per the routine practice. The patients will then be screened for the inclusion and exclusion criteria. Eligible patients will then be sent / given written information about the study. Interested patients will come for their first visit to see the endocrine specialist nurse. After obtaining written informed consent, patients will be randomised to either the block & replace group or the titrated regime group. Six weeks after having the radioactive iodine treatment, patients will be seen by the endocrine specialist nurse for their second study visit. They will then follow the treatment algorithm. Third evaluation of patients is done at 6 months and the final evaluation is done at 12 months.

At each visit patient will be asked to fill up 3 questionnaires (SF36-II, GHQ-12 & TSQ). In addition they will fill up one question on satisfaction to treatment question. They will also have blood tests for their thyroid function. The blood test is part on the routine care and is not an additional test for the study.

User involvement: We will invite 1 or 2 thyrotoxicosis patients who has already under went radioactive iodine treatment to comment on the patient information sheets. We would also be giving regular feedback to the patients during and at the end of the study.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)

Differences in the scores on SF36-II & GHQ-12 between the 2 groups at 6 weeks, 6 months and 12 months, controlling for the baseline scores

Key secondary outcome(s))
Not provided at time of registration

Completion date
31/12/2008

Eligibility

Key inclusion criteria
1. Toxic nodular thyroid disease (toxic multinodular goitre or toxic nodule)
2. Garves' thyrotoxicosis with patients' preference to have RAI
3. Recurrent Graves' thyrotoxicosis
4. Age between 18 and 80 years.

According to the current local practice, patients needing radioactive iodine treatment will be seen by our Endocrine Specialist Nurses. These patients will be assessed for their eligibility for this study. If the patients are eligible, they will be given the information sheet about the study. If they are happy to take part, before the radioactive iodine treatment, written consent will be obtained and patients will be randomised at that stage.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Pregnant or lactating women
2. Patients allergic to antithyroid drugs or iodine
3. Active thyroid eye disease
4. Known alcohol or drug abuse
5. Significant psychiatric disturbances

Date of first enrolment
13/09/2005

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Devon & Exeter Hospital (Wonford)
Exeter
United Kingdom
EX2 5DW

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Royal Devon & Exeter NHS Foundation Trust (UK)

Funder Name
NHS R&D Support Funding (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes