ISRCTN27681212 https://doi.org/10.1186/ISRCTN27681212

# 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

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
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

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Quality of life

## Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

## 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 measure
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

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
13/09/2005

### 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
140

### 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
England

United Kingdom

### 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

### Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
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SW1A 2NL
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dhmail@doh.gsi.org.uk

**Sponsor type**
Government

**Website**
http://www.dh.gov.uk/Home/fs/en

# 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

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration