

Optimum dose finding in radioiodine treatment of hyperthyroidism in Graves' disease

Submission date
23/11/2009

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
20/01/2010

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
11/10/2011

Condition category
Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
1.0

Study information

Scientific Title

12-year prospective, randomised, open-label blinded endpoint study (PROBE) to estimate the optimum dose for radioiodine treatment of Graves' disease

Study objectives

Dose optimisation in Graves' disease has been targeted such as to avoid a large number of recurrences or uncured patients. There was no particular focus on a low hypothyroidism rate. We hypothesise that there is an optimum individual dose resulting in a lowest uncured hyperthyroidism or recurrence rate and a low hypothyroidism rate at the same dose concept. An optimised dose concept would be desirable for two reasons:

1. To limit use of ¹³¹I for radiation safety issues
2. To limit hypothyroidism rate and consecutive need of replacement therapy. It seems to be an important factor in regions where patients have limited resources or, where access to medical supplies is limited.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Dongshan Ethics Committee approved in April 1997

Primary study design

Interventional

Study design

Prospective randomised open-label blinded end point study with intention-to-treat principle

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Graves' disease

Interventions

Intervention group: Participants received one application of ¹³¹I (oral), followed by a second application after 3 months, if the first was unsuccessful. The dose/activity of ¹³¹I (in MBq) was determined using a clinical score system, the gland mass, and the 24 hours uptake of a test activity. Follow up was initially two-weekly, then monthly, and, after the patient became stable in 6-monthly intervals.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Radioiodine

Primary outcome(s)

Assessed annually, that is every 12 months after first therapeutic intervention for each patient, ending year 12:

1. Euthyroidism
2. Hyperthyroidism
3. Recurrence
4. Hypothyroidism
5. Subclinical hypothyroidism

Key secondary outcome(s)

The sum dose of 131-radioiodine which was necessary to achieve therapeutic primary outcomes at the end of the study. It was assessed 3 months after inclusion and after a patient had administered or not a second treatment dose. The outcomes measure resulted from 5 groups of dose-ranges of radioiodine, beginning with a low dose-range and ending with a high dose-range. The individual dose to be administered was determined according to these 5 range groups modulated by a clinical 7 step score.

Completion date

31/12/2009

Eligibility

Key inclusion criteria

1. Newly diagnosed hyperthyroid patients diagnosed Graves' disease
2. Patients with Graves' disease and anti thyroid drugs after 2 weeks withdrawal
3. Elevated levels of a recent set of general serum and thyroid function tests, confirming hyperthyroidism
4. 24-hour 131I-uptake greater than or equal to 40%
5. If 131I-uptake less than 40%, restriction of food or drug rich in iodine, retest until uptake was greater than or equal to 40%
6. Aged 8 years to no age limit, males and females

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Other

Sex

All

Key exclusion criteria

1. Severe liver or kidney damage
2. Agranulocytosis
3. Pregnancy or lactation
4. Less than 8 years of age

Date of first enrolment

20/04/1997

Date of final enrolment

31/12/2009

Locations

Countries of recruitment

China

Study participating centre

Sun Yat-sen University

Guangzhou

China

510080

Sponsor information

Organisation

Sun Yat-Sen University (China)

ROR

<https://ror.org/0064kty71>

Funder(s)

Funder type

University/education

Funder Name

Sun Yat-Sen University (China)

Alternative Name(s)

National Guangdong University, , , SYSU

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

China

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2011		Yes	No