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

Submission date	Recruitment status	[_] Prospectively registered
23/11/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/01/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/10/2011	Nutritional, Metabolic, Endocrine	

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
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

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact either schneider_P@nuklearmedizin.uni-wuerzburg.de (for a translated English version) or chendanyun@sohu.com (for a Chinese version) to request a patient information sheet

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 measure
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

Secondary outcome measures
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 adminstered was determined according to these 5 range groups modulated by a clinical 7 step score.

Overall study start date
20/04/1997

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

Age group
Other

Sex
Both

Target number of participants
600 patients randomised to 5 groups of 120 each

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)

Sponsor details
The First Affiliated Hospital
Zhongshan Road , 1st
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Sponsor type
University/education

Website
http://www.gzsums.net/yiyxx/e-yiygaik.asp

ROR
https://ror.org/0064kty71

Funder(s)

Funder type
University/education

Funder Name
Sun Yat-Sen University (China)

Alternative Name(s)
SYSU

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
China

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

Study outputs

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