

Comparison of the efficacy of 131I versus anti-thyroid drugs in the treatment of hyperthyroidism

Submission date
13/12/2007

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
21/12/2007

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
08/04/2021

Condition category
Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

1.0

Study information

Scientific Title

A 9-year Prospective, Randomized, Open-label, Blinded End point (PROBE) treatment study to compare the efficacy of 131I versus anti-thyroid drugs in the treatment of hyperthyroidism

Study objectives

1. 131I therapy is considered cheaper, safer, simpler to use and has less side effects compared with anti-thyroid drugs
2. Time to cure hyperthyroidism using radioiodine (131I) is shorter compared with anti-thyroid drugs
3. Rate of hypothyroidism when using 131I is low, if carefully dosed

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the Dongshan Ethics Committee on 22 December 1997.

Primary study design

Interventional

Study design

Prospective, randomized, open-label, blinded end point study, with intention-to-treat principle.

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Hyperthyroidism

Interventions

Recruitment took place in the province of Guangdong, China. Participants were randomised to the intervention and control groups in equal numbers.

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 estimated using a standard procedure (mass of the lesion or gland, uptake of a test activity after 24 hours) to achieve a gland dose to cure hyperthyroidism.

Control group: Administration of an anti-thyroid drug, either methimazole (oral) or propylthiouracil (oral), as needed at a dose aimed at achieving euthyroidism, for at least 18 months. The treatment continued until primary outcome data were collected. If euthyroidism was not achieved, the patient was treated with anti-thyroid drug until the end of the study (98.4 +/- 5.5 months [range: 89 - 108 months]).

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

¹³¹I, anti-thyroid drugs (methimazole and propylthiouracil)

Primary outcome(s)

The outcomes above were assessed at monthly follow-up visits during the first year and then every 3 to 6 months thereafter. Duration of follow-up was 98.4 +/- 5.5 months (range: 89 - 108 months) for participants who were included in both primary and secondary outcomes measures.

1. Euthyroidism
2. Persistent hyperthyroidism
3. Recurrence
4. Clinical hypothyroidism
5. Subclinical Hypothyroidism

Key secondary outcome(s)

The outcomes above were assessed at monthly follow-up visits during the first year and then every 3 to 6 months thereafter. Duration of follow-up was 98.4 +/- 5.5 months (range: 89 - 108 months) for participants who were included in both primary and secondary outcomes measures.

1. Changes in ophthalmopathy and complications
2. Side effects
3. Safety
4. Efficacy

Completion date

31/01/2007

Eligibility

Key inclusion criteria

1. Newly diagnosed hyperthyroid patients
2. No previous thyroid treatment
3. Elevated levels of a recent set of general serum and thyroid function tests, indication of hyperthyroidism
4. 24-hour uptake of ¹³¹I $\geq 40\%$

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

All

Total final enrolment

460

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

01/01/1998

Date of final enrolment

31/01/2007

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		01/02/2009	08/04/2021	Yes	No