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

Submission date	Recruitment status	[ ] Prospectively registered
13/12/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
21/12/2007	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/04/2021	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Dan Yun Chen

Contact details
Sun Yat-sen University
The First Affiliated Hospital
Dongshan Division
Hyperthyroidism Treatment Center
Guangzhou
China
510080
-
chendanyun@sohu.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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.

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
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. Sbclinical Hypothyroidism

Secondary outcome measures
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

Overall study start date
01/01/1998

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 >=40%

Participant type(s)

Patient

Age group
Not Specified

Sex
Both

Target number of participants
460

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)

Sponsor details
The First Affiliated Hospital
Guangzhou

China
510080
-
chendanyun@sohu.com

Sponsor type
University/education

Website
http://www.sysu.edu.cn/en/index.html

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