

Treatment of patients with amiodarone-induced thyrotoxicosis type 2

Submission date 12/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 12/09/2005	Overall study status Completed	☐ Protocol
Last Edited 03/07/2009	Condition category Nutritional, Metabolic, Endocrine	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ 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

Protocol serial number
NTR78; MEC number: 03/271

Study information

Scientific Title

Study objectives
Not provided at time of registration

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Primary study design

Interventional

Study design

Randomised, single blind, placebo controlled, parallel group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Amiodarone-induced thyrotoxicosis type 2

Interventions

Treatment with:

1. Methimazole and prednisone
2. Methimazole and sodium perchlorate
3. Methimazole, sodium perchlorate and prednisone

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Methimazole, prednisone, sodium perchlorate

Primary outcome(s)

Achievement of euthyroidism (TSH greater than 0.4 mE/L at 3 and 6 months).

Key secondary outcome(s)

Development side-effects.

Completion date

31/12/2006

Eligibility**Key inclusion criteria**

1. Thyroid stimulating hormone (TSH) less than 0.4 mE/L
2. Free thyroxine (FT4) greater than 25 pmol/l
3. Normal or raised triiodothyronine (T3)
4. Thyroid peroxidase antibodies less than 50 kU/l
5. Thyroid binding inhibitory immunoglobulins (TBII) less than 2.0 kU/l

6. Amiodarone use
7. Poor or no visualisation of thyroid gland on 99mTc-pertechnetate scintigraphy
8. No nodular goiter on ultrasound

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Very critical illness
2. Drug or alcohol abuse
3. Pregnancy
4. No informed consent

Date of first enrolment

01/03/2004

Date of final enrolment

31/12/2006

Locations**Countries of recruitment**

Netherlands

Study participating centre

Academic Medical Center

Amsterdam

Netherlands

1105 AZ

Sponsor information**Organisation**

Academic Medical Centre (AMC) (Netherlands)

ROR

<https://ror.org/03t4gr691>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Academic Medical Centre (AMC) (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration