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Treatment of patients with amiodarone-induced thyrotoxicosis type 2

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

Study design
Randomised, single blind, placebo controlled, parallel group trial

Primary study design
Interventional

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