A Multi-Center, Single-Blind, Randomized Study Comparing Thymectomy to No Thymectomy in Non-Thymomatous Myasthenia Gravis (MG) Patients Receiving Prednisone

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The purpose of this 5-year trial is to determine if the surgical procedure, extended transsternal thymectomy (ETTX), combined with prednisone therapy is more beneficial in treating individuals with non-thymomatous MG than prednisone therapy alone.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	Interventional

Summary

ID

NL-OMON30649

Source
ToetsingOnline

Brief title
TxMG trial

Condition

- Autoimmune disorders
- Muscle disorders

Synonym
myasthenia, myasthenia gravis

Research involving
Human

Sponsors and support

Primary sponsor: National Institute of Health
Source(s) of monetary or material Support: National Institute of Health (NIH);USA

Intervention

Keyword: myasthenia gravis, prednisone, thymectomy

Outcome measures

Primary outcome

The primary objective is to determine in the non-thymomatous MG patient population studied wether ETTX combined with prednisone therapy should be preferred to prednisone therapy alone.

Secondary outcome

The secondary objectives are (i) to determine the efficacy of the therapies by documenting their effects on myasthenic weakness and (ii) to determine their safety by documenting total exposure to prednisone and by reecording the Trial Specific Adverse Events (TSAEs) and Adverse Symptoms (TSASs). Importantly, we shall also investigate wether outcomes vary between different subgroups by the following planned sub-group analyses:

-use of corticosteroids vs. none prior to entering the study

-male versus female

-age < 40 years and age > 40 years at disease onset

Study description

Background summary

Myasthenia gravis (MG) is an autoimmune disease involving the thymus in which

85 percent of patients have antibodies to muscle acetylcholine receptors (AChR-Ab) that interfere with neuromuscular transmission. MG frequently causes severe disability that can be life-threatening. Thymectomy*a surgical procedure that removes thymus gland tissue from the chest cavity*has been an established therapy for non-thymomatous MG, or MG without thymoma, for more than 60 years (based on retrospective, non-randomized studies). Corticosteroids are now being used increasingly either as the sole treatment or in combination with thymectomy. Both therapies have associated adverse effects and indications for their use based on randomized trial data are lacking.

Study objective

The purpose of this 5-year trial is to determine if the surgical procedure, extended transsternal thymectomy (ETTX), combined with prednisone therapy is more beneficial in treating individuals with non-thymomatous MG than prednisone therapy alone.

Study design

A Multi-Center, Single-Blind, Randomized Study Comparing Thymectomy to No Thymectomy in Non-Thymomatous Myasthenia Gravis (MG) Patients Receiving Prednisone

Intervention

Study participants will be randomized either to undergo the surgical procedure ETTX and receive prednisone treatment, or to receive prednisone treatment alone without surgery. Participants will be followed for at least 3 years.

Study burden and risks

There is no increased risk for the patients. Thymectomy and immunosuppressive treatment are now routinely used in the treatment of myasthenia gravis.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Male and female MG patients aged 18 to 60 years inclusive (thymectomy is not regularly performed in non-thymomatous MG patients > 60 years of age).
Onset of generalized MG within the last 3 years.
Positive serum anti-acetylcholine receptor binding antibodies (AChR Ab <=/> 1.0 nmol/L).
MGFA class II-IV at entry, using the MG Foundation of America (MGFA) classification, while receiving optimal anti-cholinesterase treatment with or without oral prednisone.

Exclusion criteria

Ocular MG without generalized weakness (MGFA Class I) or minimal weakness that would not require the use of corticosteroids.
Myasthenic weakness requiring intubation (MGFA class V) in the prior month.
Immunosuppressive therapy other than corticosteroids in the preceding year.
Medically unfit for thymectomy.
Chest computertomogreaphy evidence for thymoma.
Pregnancy or lactation; contraindications to the use of corticosteroids; unwillingness to practice effective contraception.
A serious concurrent medical, neurological or psychiatric condition.
Current daily dose of prednisone of more than 50 mg.
Participation in another experimental clinical trial.
History of alcohol or drug abuse.
Unwillingness or inability to comply with the requirements of the protocol.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-09-2008
Enrollment:	5
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ISRCTN	ISRCTN78813854enNCT00294658
CCMO	NL15086.058.07