An alternative approach for treatment of infantile esotropia with botulinum toxin A.

Published: 19-11-2012
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To determine the proportion of successful alignment after treatment of infantile esotropia with Botox.

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

Summary

ID

NL-OMON39876

Source
ToetsingOnline

Brief title
Botox in infantile esotropia.

Condition

- Ocular neuromuscular disorders

Synonym
infantile esotropia, squinting

Research involving
Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam
Source(s) of monetary or material Support: Allergan,Stichting Wetenschappelijk Onderzoek Oogziekenhuis.

Intervention

Keyword: Botox, infantile esotropia, strabism surgery

Outcome measures

Primary outcome

Proportion of successful motor alignment at six months.

Secondary outcome

Binocular function.

Time of onset esotropia.

Percentages and duration of ptosis and exotropia (temporary side effects of

botulinum injection).

Percentages of reinjection and additional alignment surgery.

BCVA at each visit and amblyopia.

Occurrence of vertical disturbances of ocular motility.

Adverse events.

Study description

Background summary

In comparison to standard strabism surgery in patients with infantile esotropia, bilateral injection of Botox in the medial rectus muscle is conjectured to be equivalent with respect to motor alignment, while burden and risk are (because less invasive) expected to be less.

Study objective

To determine the proportion of successful alignment after treatment of infantile esotropia with Botox.

Study design

Prospective case series.

Intervention

Bilateral injection of Botox in the medial rectus muscle.

Study burden and risks

As an alternative to conventional strabism surgery, treatment with Botox may be equally effective while both burden and risk are anticipated to be reduced.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Children (2-11 years)

Inclusion criteria

- Infantile esotropia; age < 6 years,
- No known/established neurological disease.
- No vertical deviation (no upshoots).
- Non-accommodative (less than 3D spherical equivalent hyperopia).
- Up to 40 * esotropia.
- Free alternators.
- Difference in refraction between both eyes * 1.5 D.

Exclusion criteria

- Previous strabismus surgery.
- Retinal disease.
- Any medical condition that would preclude general anesthesia with sevoflurane.
- Hypersensitivity to any Botox ingredient.
- Muscular disease such as myasthenia gravis or Eaton-Lambert syndrome.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-12-2013
Enrollment:	40
Type:	Actual

Medical products/devices used

Product type:	Medicine

Brand name:	Botox
Generic name:	botulinum toxin type A
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	19-11-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	08-04-2013
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 24276
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2012-005068-82-NL
CCMO	NL42631.078.12
OMON	NL-OMON24276