A prospective, randomized, double-blind comparison of 5 % against 1.25 % povidone-iodine solution in preoperative antisepsis for strabismus surgery in young children.

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To compare the efficacy of 5 % vs. 1.25 % povidone-iodine (PI) as preoperative antiseptic prior to strabismus surgery in children as a prophylaxis of endophthalmitis. Given the low rate of endophthalmitis the conjunctival bacterial flora rate is...

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

Summary

ID

NL-OMON30444

Source
ToetsingOnline

Brief title
1.25% vs 5% povidone-iodine antisepsis for strabismus surgery in children

Condition

- Ocular neuromuscular disorders

Synonym
strabismus squint

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: endophthalmitis, preoperative antisepsis, strabismus surgery

Outcome measures

Primary outcome

The difference in the mean numbers of bacterial colony forming units (CFUs)

from pre-irrigation (I) to post-irrigation with PI (2-4).

Secondary outcome

Iodine excretion after surgery, assessed as urine iodine concentration per

creatinine clearance.

Postoperative erosion of the cornea and corneal oedema. Both of these have been

described as side-effects of PI use.

Study description

Background summary

Endophthalmitis after strabismus surgery in young children leads to blindness and loss of the affected eye. It is caused by conjunctival bacteria. PI solutions between 1% and 5% reduce the number of bacteria on the conjunctiva. The concentration used varies widely among clinics, from 1% to 5%. In vitro studies have shown that PI is paradoxically more effective at lower concentration, but in cataract surgery in elderly, 1% PI has been shown to be less effective than 5% PI. Dilution by tear fluid or binding of PI to proteins in tear fluid may lower its effectiveness. Since endophthalmitis after strabismus surgery especially affects young children and the bacterial flora of the conjunctiva in children is different from that in adults, the cataract PI study should be repeated in young children operated for strabismus.

Study objective

To compare the efficacy of 5 % vs. 1.25 % povidone-iodine (PI) as preoperative antiseptic prior to strabismus surgery in children as a prophylaxis of endophthalmitis. Given the low rate of endophthalmitis the conjunctival bacterial flora rate is used as surrogate marker to determine the effectiveness of topical PI in reducing or eliminating bacteria from the ocular surface at the time of the surgery.

Study design

The study is a multi-centre, prospective, randomized-controlled, parallel-groups, assessor-blind (microbiological assessments), investigator-initiated trial.

Intervention

Diluted PI, 1.25% or 5%, will be prepared in a sterile fashion, and distributed in single-use dispensers. These will be coded for randomization. Before initiation of surgery, children randomized to the 5% PI group will have their conjunctival fornices irrigated with 5 ml PI 5%. Children randomized to the 1.25% PI group will have their conjunctival fornices irrigated with 5 ml PI 1.25%. Conjunctiva cultures for aerobic and anaerobic bacteria will be obtained (1) after general anaestheasia has been established, (2) 5-10 min after PI irrigation, (3) after reattachment of the eye muscles and (4) after closing the conjunctiva with sutures.

Study burden and risks

Risks are limited to the act of taking the four bacterial cultures, as both 1.25% PI and 5% PI are approved preoperative antiseptic applications of PI and both are used, rather indiscriminately, by the university departments of ophthalmology participating in the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

(1) Children < 6 years of age (2) undergoing surgery for strabismus for the first time, including any recession and/or resection surgery of the medial and/or lateral rectus muscles. (3) Children willing to take part in all aspects of the study and written informed consent on the study participation of the child provided by the parents.

Exclusion criteria

(1) Any history or current condition of hypersensitivity to iodine. (2) Children on topical antibiotic within the last 30 days. (3) Children with signs of acute conjunctivitis, blepharitis, dacryocystitis or respiratory infection within the last 30 days. (4) Children with asthma or similar chronic, obstructive pulmonary disorder (5) Insufficiently treated amblyopia, i.e. visual acuity must be equal in both eyes or not differ by more than 1 LogMAR line (or equivalent in preverbal children).

Study design

Design

Study phase:	4
Study type:	Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-09-2009
Enrollment:	100
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Betaisodona (TM) (= 10% povidone-iodine solution to be diluted to 1.25%)
Generic name:	10% povidone-iodine solution to be diluted to 1.25%
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Betaisodona (TM) (= 10% povidone-iodine solution to be diluted to 5%)
Generic name:	10% povidone-iodine solution to be diluted to 5%
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	05-09-2007
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	01-04-2008
Application type:	First submission

Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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
EudraCT	EUCTR2006-004811-22-NL
CCMO	NL14357.000.07