A study of beneficial and adverse effects of Dermabond tissue adhesive for episcleral explants in retinal detachment surgery.

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Evaluation of the hypothesis that outcomes of Dermabond tissue adhesive and conventional suturing for securing episcleral explant in retinal detachment surgery are equivalent.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Retina, choroid and vitreous haemorrhages and vascular disorders
Study type	Observational non invasive

Summary

ID

NL-OMON31281

Source
ToetsingOnline

Brief title
Dermabond versus scleral sutures.

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
retinal detachment

Research involving
Human

Sponsors and support

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

Oogziekenhuis - Prof. Dr. H. J. Flieringa.

Intervention

Keyword: Octyl-cyanoacrylate, Retinal detachment, Scleral explant

Outcome measures

Primary outcome

Position of the scleral indentation;

Redness of the conjunctiva;

Baring of the explant;

Subjective assessment of complaints.

Secondary outcome

NA.

Study description

Background summary

To achieve scleral indentation, episcleral explants are traditionally fastened on the sclera by sutures. Sutures, however, carry the potential risk of perforation which may result in severe complications. Octyl-cyanoacrylate (Dermabond) has been used in patients with a thin sclera (a strong incentive for tissue adhesive rather than sutures). Our impression was that the explant remained securely attached and that follow-up findings were normal.

Study objective

Evaluation of the hypothesis that outcomes of Dermabond tissue adhesive and conventional suturing for securing episcleral explant in retinal detachment surgery are equivalent.

Study design

Retrospective case series.

Study burden and risks

Burden is limited to a single extra visit which will take about 30 minutes.
Risks are negligible.

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

- Age >= 18 years of age.
- Informed consent.
- Episcleral explant (December 2005 or later).

Exclusion criteria

None.

Study design

Design

Study type:	Observational non invasive
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):	04-03-2008
Enrollment:	75
Type:	Actual

Ethics review

Approved WMO

Date:	29-11-2007
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

No registrations found.

In other registers

Register	ID
CCMO	NL17958.078.07