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

Published: 29-11-2007 Last updated: 08-05-2024

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

1 - A study of beneficial and adverse effects of Dermabond tissue adhesive for episc ... 25-05-2025

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

Public

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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