# Upper eyelid blepharoplasty investigating 3D and functional outcomes

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The aim of this study is to objectively assess 3D and functional outcomes of upper blepharoplasty on periorbital volume, dry eyes, peripheral vision, electrical activity of the frontal muscles and wellbeing in two different surgical techniques.

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Other condition |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON44420

**Source**
ToetsingOnline

**Brief title**
Upper eyelid blepharoplasty investigating 3D and functional outcomes

### Condition

- Other condition

**Synonym**
blepharochalasis, excess skin upper eyelid

**Health condition**

blefarochalasis, huidoverschot van de bovenoogleden

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Blepharoplasty, Three-dimensional imaging

## Outcome measures

### Primary outcome

The primary endpoint is orbital change in volume.

### Secondary outcome

Secondary outcomes are electrical activity of the frontal and orbicularis oculi

muscles, peripheral vision, presence and severity of dry eyes, quality of life

and wellbeing.

# Study description

### Background summary

Blepharoplasty of the upper eyelids is one of the most commonly performed surgical procedures in aesthetic surgery. This surgery may be performed for aesthetic reasons, but also for functional indications. Based on the existing literature, the outcomes of an upper blepharoplasty might depend on the peri-orbital volume and the surgical technique applied. The traditional technique of upper blepharoplasty consists of the resection of skin and a strip of the orbicularis oculi muscle, and coagulation of fat. A common alternative technique involves the removal of skin only (alternative). The outcomes (esthetic and functional) between these techniques may vary. Both techniques are widely used in daily practice. However, there is yet no consensus about which technique is preferable.

### Study objective

The aim of this study is to objectively assess 3D and functional outcomes of upper blepharoplasty on periorbital volume, dry eyes, peripheral vision, electrical activity of the frontal muscles and wellbeing in two different

surgical techniques.

### Study design

The study design is a clincial trial. Patients are randomized in the *traditional* (resection of skin and strip of the orbicularis oculi muscle)or *alternative* (skin only ) blepharoplasty treatment group. The investigators and patients are blinded during the study. Patients undergo a series of functional tests and 3D photography pre- and postoperatively. The follow up is 12 months.

### Intervention

Patients undergo a blepharoplasty.

### Study burden and risks

Both surgical techniques are common techniques for a upper blepharoplasty, widely used and considered not to be harmful. Specific for this study, the patient have to undergo a series of non-invasive tests. Completing these tests cost the patients 45 minutes extra per visit. During the one year follow-up, the participants have to visit the clinic 4 times of which 2 visits are combined their regular control appointments (standard care).

## 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

- Blepharochalasis of both eyes
- Age between 30 and 60
- Caucasian
- Both male and female patients are included
- Correction of vision between -6 and +6
- Vision of 0.5 or better (with correction)
- Fluent in Dutch
- Legally capable

## Exclusion criteria

- Protruding medial fat compartment
- Ocular trauma in past
- Trauma of the orbital region in the past
- A medical history of eyelid surgery or surgery in the region of the eyebrows.
- Any current ophthalmic disease that could interfere with the ophthalmic tests
- Horner syndrome
- Blepharoptosis
- Graves* disease
- Myasthenia Gravis
- Recent (in the past 6 months) botulin toxin treatment in the upper face
- Nasolacrimal duct obstruction
- Epilepsy
- Retinal defects/diseases that cause visual field defects

# Study design

## Design

**Study type:** Interventional

| | |
|---|---|
| Masking: | Double blinded (masking used) |
| Control: | Uncontrolled |
| Primary purpose: | Other |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 20-02-2018 |
| Enrollment: | 54 |
| Type: | Actual |

# Ethics review

Approved WMO

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|---|---|
| Date: | 17-11-2017 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |

# 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 | NL62635.042.17 |