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Functional and psychosocial benefits of blepharoplasty

Submission date	Recruitment status	[_] Prospectively registered
27/02/2014	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/03/2014	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/06/2020	Eye Diseases	

Plain English summary of protocol

Background and study aims
Removing excess skin from the upper eyelids (dermatochalasis) is one of the most commonly performed eyelid surgeries in Denmark. Patients who are referred for surgery may complain of heavy eyelids, headache due to permanent lifting of the forehead, and compromised visual fields. The increasing cost of public healthcare has made it necessary to apply a new guideline to distinguish patients who are entitled to undergo a surgery subsidized by the national healthcare system. However, the guideline itself states that it is rather complicated to apply the same criteria for every single individual. Therefore, this study aims to provide a better understanding of the functional and social benefits of this eyelid surgery. This way we can hopefully apply better and more individualized criteria for admittance for eyelid surgery in a public hospital setting.

Who can participate?
Patients aged over 18 years with dermatochalasis referred by an ophthalmologist or primary physician.

What does the study involve?
The study involves a regular eye assessment along with photo documentation and visual field testing. Patients will receive a questionnaire discussing the functional and social impact of their heavy eyelids. Surgeons will remove the excess skin from the upper eyelids. 3 months after surgery patients will have a control eye examination, photo documentation and visual field testing. Patient will also fill out the same questionnaire 3 months after the operation.

What are the possible benefits and risks of participating?
The possible benefits for the patient are an extended eye examination and an extra control assessment at 3 months after surgery. The studys risk does not exceed the risk of a regular skin removal operation (blepharoplasty).

Where is the study run from?
Our study will run at the Department of Ophthalmology, Thy-Mors Hospital in Thisted, Denmark.

When is the study starting and how long is it expected to run for?
The study will run from March 2014 to March 2015.

Who is funding the study?
The study is fully financed by the Department of Ophthalmology, Thy-Mors Hospital, Denmark.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Functional and psychosocial benefits of blepharoplasty - evaluated by objective and subjective outcome measures

Study objectives
To investigate the functional and psychosocial benefits of blepharoplasty, in order to evaluate the visitation guidelines for blepharoplasty from the Danish Health and Medicines Authority.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional Ethics Committee of North Jutland (Den Videnskabsetiske Komité for Region Nordjylland), 08/10/2013

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Dermatochalasis, blepharoplasty

Interventions
Upper eyelid blepharoplasty

Before surgery and 3 months after surgery:
1. Questionnaire concerning the functional and psychosocial impact of their eyelids
2. Standard eye exam including visual acuity measured using the Snellen Chart, slit lamp examination and indirect ophthalmoscopy
3. Photographic documentation using a normal camera and the infrared camera of the Spectralis OCT scanner.
Measurements of the eye include marginal reflex distance (MRD), eye fissure height, eye fissure width, upper lid sulcus height, upper lid height, iris diameter and upper iris radius visible
4. Automatic perimetry using the blepharoptosis program

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Change in eyelid morphology after surgery
2. Change in visual field after surgery

Outcome measures will be assessed at baseline (surgery day) and 3 months after the surgery.

Secondary outcome measures
1. Change in functional problems caused by dermatochalasis after surgery
2. Change in psychosocial problems causes by dermatochalasis after surgery
3. Patient satisfaction compared to change in MRD, change in functional problems, change in psychosocial problems and change in visual field

Outcome measures will be assessed at baseline (surgery day) and 3 months after the surgery.

Overall study start date
01/03/2014

Completion date
01/03/2015

Eligibility

Key inclusion criteria
Patients aged over 18 years with dermatochalasis meeting the Danish visitation guidelines for blepharoplasty on a functional indication

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

Total final enrolment
45

Key exclusion criteria
1. Aged under 18 years
2. Inability or unwillingness to answer the questionnaires or attend the 3-month follow-up
3. Visual acuity < 0.5

Date of first enrolment
01/03/2014

Date of final enrolment
01/03/2015

Locations

Countries of recruitment
Denmark

Study participating centre
Højtoftevej 2
Thisted
Denmark
7700

Sponsor information

Organisation
Thy-Mors Hospital (Denmark)

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Thy-Mors Hospital (Denmark)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2017	25/06/2020	Yes	No