

High-frequency radio-wave electrosurgery versus simple conjunctival resection for conjunctivochalasis

Submission date 30/11/2016	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 08/12/2016	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 11/06/2018	Condition category Eye Diseases	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Conjunctivochalasis is a common eye condition where the conjunctiva (the membrane that lines the inside of the eyelids and covers the white of the eye) becomes loose and forms excess folds. This can cause eye irritation, pain, bleeding, watering, dry eye, or ulcers. Currently there are several treatments, such as simple excision (surgery) and high-frequency radio-wave electrosurgery, where an electrode is used to remove excess conjunctiva. The aim of this study is to compare how well these treatments work.

Who can participate?

Patients aged 50 to 100 with conjunctivochalasis

What does the study involve?

Participants are randomly allocated to two groups to undergo either simple excision or high-frequency radio-wave electrosurgery for conjunctivochalasis. They are then followed up for 6 months, during which their eye symptoms are assessed using eye examinations and questionnaires.

What are the possible benefits and risks of participating?

Participants may benefit from relief of their conjunctivochalasis symptoms. The risks of participating are the same as for general eye surface surgery, including bleeding, swelling and infection.

Where is the study run from?

Chang Gung Memorial Hospital (Taiwan)

When is the study starting and how long is it expected to run for?

February 2013 to March 2015

Who is funding the study?

Chang Gung Medical Research Foundation (Taiwan)

Who is the main contact?
Dr Ju-Wen Yang

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
CMRPG2C0051, CMRPG2C0052

Study information

Scientific Title
A prospective study comparing the efficacy of high-frequency radio-wave electrosurgery versus simple conjunctival resection for treatment of conjunctivochalasis

Study objectives
Conjunctivochalasis (CCh) is a common cause of ocular surface irritation in older populations. It is defined as redundant and loose inferior bulbar conjunctiva tissue interposed between the globe and the lower eyelid. CCh causes insufficient tear drainage and delayed tear clearance. In tear-sufficient eyes, CCh may present with intermittent epiphora. In dry eyes, it may exacerbate dry eye-related inflammation.

High-frequency radio-wave electrosurgery is a minimally invasive procedure to treat symptomatic conjunctivochalasis (CCh). Theoretically, it provides an effective treatment for CCh. The aim of this study is to study compare the efficacy of high-frequency radio-wave electrosurgery versus simple conjunctival resection for treatment of conjunctivochalasis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee at the Chang Gung Memorial Hospital, 26/11/2012, ref: 100-2782A3

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Conjunctivochalasis

Interventions

Patients are randomized into two groups according to their medical record numbers. The even numbers receive high-frequency radio-wave electro-surgery (Group I) and the odd numbers receive simple conjunctival resection (Group II).

Before surgery, all cases undergo a full medical and ocular history and a detailed ocular examination, including measurement of (best corrected) visual acuity, intraocular pressure measurement, slit-lamp examination and photography, fluorescein staining, tear break-up time and Schirmer test.

Conjunctivochalasis is graded preoperatively and postoperatively on the basis of the grading system (Grade 0 = no persistent fold; Grade 1 = a single, small fold; Grade 2 = 2 folds, but not higher than the tear meniscus; Grade 3 = multiple folds and higher than the tear meniscus) proposed by Meller and Tseng. Grading is done separately for the temporal, middle, and nasal areas of the conjunctiva.

Epiphora and dry eye symptoms are specifically evaluated. Dry eye symptoms are assessed with the Ocular Surface Disease Index (OSDI; Allergan, Inc., Irvine, CA,) a 12-item questionnaire designed to assess the severity of symptoms. The 12 items of the OSDI questionnaire are graded on a scale of 0 to 4: 0 = never; 1 = some of the time; 2 = half of the time; 3 = most of the time; and 4 = all the time. The total OSDI score is then calculated with the following formula: $OSDI = ([\text{sum of scores for all questions answered}] \times 100) / ([\text{total number of questions answered}] \times 4)$. Thus, the OSDI is scored on a scale of 0 to 100, with higher scores representing greater disability.

After the procedure, patients were examined postoperatively after 1 week, 1 month, 3 months and 6 months. During each postoperative visit, changes in the patients' symptoms are recorded in addition to routine examinations and photography.

At 3 months and 6 months after the surgery, the patient's symptoms are reassessed with the OSDI.

Intervention Type

Procedure/Surgery

Primary outcome(s)

1. Conjunctivochalasis, assessed by slit lamp examination using the grading system proposed by Meller and Tseng at baseline, 1 week, 1 month, 3 months and 6 months
2. Dry eye symptoms, assessed with the Ocular Surface Disease Index (OSDI) score at baseline, 3 months and 6 months

Key secondary outcome(s)

No secondary outcome measures

Completion date

01/03/2015

Eligibility

Key inclusion criteria

1. Adult patients aged 50 to 100 with symptomatic CCh
2. Willing to receive surgical treatment

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. History of conjunctival surgery
2. Nasolacrimal duct obstruction
3. Without consent

Date of first enrolment

19/03/2013

Date of final enrolment

01/09/2014

Locations

Countries of recruitment

Taiwan

Study participating centre

Chang Gung Memorial Hospital

Keelung City

Taiwan

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Sponsor information

Organisation

Chang Gung Medical Research Foundation

ROR

<https://ror.org/02verss31>

Funder(s)

Funder type

Research organisation

Funder Name

Chang Gung Medical Research Foundation (CMRPG2C0051 and CMRPG2C0052)

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study are available from Dr Ju-Wen Yang on reasonable request.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		07/12/2016	04/01/2017	No	No