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

Submission date
30/11/2016

Recruitment status
No longer recruiting

Registration date
08/12/2016

Overall study status
Completed

Last Edited
11/06/2018

Condition category
Eye Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

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 electrosurgery (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 = ([sum of scores for all questions answered] x 100)/([total number of questions answered] x 4). Thus, the OSDI is scored on a scale of 0 to 100, with higher scores representing greater disability.

After the procedure, patients was 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 measure
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

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/02/2013

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

Age group
Adult

Sex
Both

Target number of participants
10

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
204

Sponsor information

Organisation
Chang Gung Medical Research Foundation

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Department of Medical Research
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Sponsor type
Research organisation

ROR
https://ror.org/02verss31

Funder(s)

Funder type
Research organisation

Funder Name
Chang Gung Medical Research Foundation (CMRPG2C0051 and CMRPG2C0052)

Results and Publications

Publication and dissemination plan
The results will be published in an ophthalmic medical journal as soon as possible.

Intention to publish date
31/12/2019

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