Comparison of the effect of Tea tree oil with baby shampoo in Meibomian gland dysfunction treatment

Protocol summary

Study aim
To compare the effects of Tea Tree Oil (TTO) shampoo on treatment of meibomian gland dysfunction (MGD) signs and symptoms with baby shampoo

Design
Two arm parallel group randomised clinical trial, one way blinded (physician, researcher, data analyst and outcome assessor). Randomization was based on the simple random sampling method (lot).

Settings and conduct
This study was done at Khatam-al-Anbia eye hospital in Mashhad, Iran. Forty patients with MGD were treated by daily lid scrubbing with TTO shampoo in one eye and baby shampoo in the other eye. The solutions were packed in identical cans and labeled A and B. By drawing lots, it was determined that which solution to be used in which eye. Physician and patients were unaware of the contents of the containers until the end of the study. Before treatment and then after 1 and 3 months, the effect on ocular surface symptoms, tear production and stability, and conjunctival and lid signs were compared between two eyes.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients with MGD aged 18 to 70 years
Exclusion criteria: systemic medications affecting tear production, any topical medication such as steroids during last four weeks, ocular surgery, other ocular or systemic diseases involving ocular surface, infectious keratoconjunctivitis, and contact lenses.

Intervention groups
Intervention group 1: right or left eye of patients with MGD who received solution A (TTO). Intervention group 2: right or left eye of patients with MGD who received solution B (baby shampoo).

Main outcome variables
DEQ5 questionnaire, redness, conjunctiva and corneal staining by oxford scoring system, tear break-up time, lid margin vascularity, plugging and capping of gland orifices, Schirmer1, meibum quality and expressibility of glands, possible side effects

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: IRCT20201219049753N1
Registration date: 2020-12-26, 1399/10/06
Registration timing: retrospective

Last update: 2020-12-26, 1399/10/06
Update count: 0

Registration date
2020-12-26, 1399/10/06

Registrant information
Name
Ghodsieh Zamani
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2014-04-05, 1393/01/16

Expected recruitment end date
2014-10-02, 1393/07/10

Actual recruitment start date
2014-04-05, 1393/01/16

Actual recruitment end date
2014-10-02, 1393/07/10

Trial completion date
Scientific title
Comparison of the effect of Tea tree oil with baby shampoo in Meibomian gland dysfunction treatment

Public title
Effect of Tea tree oil in treatment of Meibomian gland dysfunction

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Adult patients aged 18 to 70 years with meibomian gland dysfunction diagnosis in slit-lamp examination

Exclusion criteria:
Systemic medications affecting tear production (antihistamines, antidepressants and etc.) Contact lenses
Eyelid malfunction such as lagophthalmous History of ocular surgery Other ocular diseases involving ocular surface (Stevens-Johnson, Sjogren's syndrome, chemical damage, history of head radiation) Systemic diseases involving ocular surface (Diabetes mellitus, rosacea, neurologic diseases) Infectious keratoconjunctivitis Any topical medication such as steroids during last four weeks

Age
From 18 years old to 70 years old

Gender
Both

Phase
3

Groups that have been masked
- Care provider
- Investigator
- Outcome assessor
- Data analyst

Sample size
Target sample size: 40
More than 1 sample in each individual
Number of samples in each individual: 2
Right eye and left eye
Actual sample size reached: 40
More than 1 sample in each individual
Actual sample size in each individual: 2
Right eye and left eye

Randomization (investigator's opinion)
Randomized

Randomization description
Patients received baby oil or TTO shampoo for each eye randomly based on the simple random sampling method. Two boxes were labeled with A and B by the manufacturer. In each box we had containers with same solution (TTO or baby shampoo). For each patient, A and B was determined by lot for the eyes.

Blinding (investigator's opinion)
Single blinded

Blinding description
Physician was unaware of the contents of the containers. Physician was researcher, outcome assessor and data analyst. Shampoos were slightly different in color, consistency and odor and could not be completely simulated. The patient was aware that two different solutions were prescribed for rinsing the eyes but he/she did not know which solution was used for which eye.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Ethics committee, Medical sciences faculty, Pardis, Vakil abad blvd.
City
Mashhad
Province
Razavi Khorasan
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Approval date
2014-03-15, 1392/12/24

Health conditions studied

1

Description of health condition studied
Meibomian gland dysfunction
ICD-10 code
H02.88
ICD-10 code description
Meibomian gland dysfunction of eyelid

Primary outcomes

1

Description
Ocular surface symptoms score in DEQ5 questionnair
Timepoint
At first (before treatment), one and three months after treatment

Method of measurement
DEQ5 questionnair

2

Description
conjunctival redness

**Timepoint**
At first (before treatment), one and three months after treatment

**Method of measurement**
Conjunctival vessel dilation and hyperemia

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3

**Description**
Fluorescein staining of the cornea and conjunctiva

**Timepoint**
At first (before treatment), one and three months after treatment

**Method of measurement**
Oxford scoring system after fluorescein staining

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4

**Description**
Tear break up time in second

**Timepoint**
At first (before treatment), one and three months after treatment

**Method of measurement**
After applying fluorescein dye, the patient blinks several times and then we ask her/him not to blink anymore. We record the time of the first dark spot in the tear on the surface of the cornea in seconds.

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5

**Description**
Lid margin vascularity

**Timepoint**
At first (before treatment), one and three months after treatment

**Method of measurement**
Existence of telangiectasia at the edge of the eyelid on slit lamp examination

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**Description**
Plugging of meibomian gland orifices

**Timepoint**
At first (before treatment), one and three months after treatment

**Method of measurement**
Existence of elevation of meibomian gland orifices in slitlamp examination

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7

**Description**
Capping of meibomian gland orifices

**Timepoint**
At first (before treatment), one and three months after treatment

**Method of measurement**
Existence of oil droplets on lid margin

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8

**Description**
Tear production in the Schirmer1 test

**Timepoint**
At first (before treatment), one and three months after treatment

**Method of measurement**
Wetting of the Shermer strip in millimeters after 5 minutes in the lower fornix between the inner two-thirds and the outer third (with out topical anesthetic)

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9

**Description**
Meibomian gland expressibility

**Timepoint**
At first (before treatment), one and three months after treatment

**Method of measurement**
It was determined by simultaneous expression from approximately eight glands (occupying central one third of the lower lid length) by firm digital pressure. It was scored according to the number of the eight glands from which a fluid secretion can be expressed, regardless of its qualitative appearance (0 = all glands expressible, 1 = 3-4 glands expressible, 2 = 1-2 glands expressible, 3 = no glands expressible).

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10

**Description**
Meibum quality

**Timepoint**
At first (before treatment), one and three months after treatment

**Method of measurement**
Quality of expressed lipid was evaluated in appearance and scored as follows; clear fluid (0), cloudy fluid (1), viscous fluid containing particulate matter (2) and densely opaque, inspissated, toothpaste-like material (3). Meibum quality score was defined by summation of scores of expressed glands.

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**Description**
Occurrence of possible side effects

**Timepoint**
At first (before treatment), one and three months after treatment

**Method of measurement**
Occurrence of itching, burning, redness and irritating symptoms of eyes and eyelid skin after starting treatment

**Secondary outcomes**
empty

**Intervention groups**
1

Description
Intervention group 1: Ophthalmic cleansing shampoo containing TTO (EYESOL), once a day, for three months. After washing hands, a cotton bud was to be moistened with the solution. Then, with the index finger of the other hand, he/she must gently hold down the lower eyelid and look up. Eyelashes and eyelid margin were to be rubbed gently with the bud for 60–90s. Afterwards, he/she must gently hold up the upper eyelid and look down and rub upper eyelid margin. After each application, eyes and eyelids were to be rinsed thoroughly with clean water.

Category
Treatment - Drugs

2

Description
Intervention group 2: JOHNSON’S® baby shampoo, once a day, for three months. After washing hands, a cotton bud was to be moistened with the solution. Then, with the index finger of the other hand, he/she must gently hold down the lower eyelid and look up. Eyelashes and eyelid margin were to be rubbed gently with the bud for 60–90s. Afterwards, he/she must gently hold up the upper eyelid and look down and rub upper eyelid margin. After each application, eyes and eyelids were to be rinsed thoroughly with clean water.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Khatam Al-Anbia Eye Hospital
Full name of responsible person
Ghodsieh Zamani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person

Person responsible for scientific inquiries
Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Ghodsieh Zamani
Position
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Latest degree
Specialist
Other areas of specialty/work
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Ghodsieh Zamani

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Latest degree
Specialist

Other areas of specialty/work
Ophthalmology

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Sharing plan
Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data is potentially shareable after unidentified individuals.

When the data will become available and for how long
The start of the access period is after the results are published.

To whom data/document is available
Researchers working in academic and scientific institutions can have access.

Under which criteria data/document could be used
They can use the data to get acquainted with the type of data classification and statistical analysis.

From where data/document is obtainable
Sending an email to the researcher in charge of the study zamanigh@mums.ac.ir

What processes are involved for a request to access data/document
The request will be sent via an email to the researcher in charge of studying, and after reviewing the request by the research team and final approval, the data will be sent within a month.

Comments