Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

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

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3728 1401

Email address

zamanigh@mums.ac.ir

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

2014-12-31, 1393/10/10

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 analyser

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 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

Postal code
91735951

Approval date
2014-03-15, 1392/12/24

Ethics committee reference number
99/310743

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

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

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.

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

6

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

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

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)

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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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.

11

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

Street address
Khatam Al-Anbia Eye Hospital, Aboutaleb Intersection

City
Mashhad

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Postal code
9195965919

Phone
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Email
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Saeid Eslami

Street address
Ghoreyshi building, Daneshgah Ave.

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9195965919

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ramresearch@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Mashhad University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Ghodsieh Zamani

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Ophthalmology

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Position
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Specialist
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Person responsible for updating data

Contact
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Mashhad University of Medical Sciences
Full name of responsible person
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Specialist
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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