

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 lagophthalmos 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 questionnaire

Timepoint

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

Method of measurement

DEQ5 questionnaire

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 Schirmer 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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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.

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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

Street address

Khatam Al-Anbia Eye Hospital, Aboutaleb Intersection

City

Mashhad

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Razavi Khorasan

Postal code

9195965919

Phone

+98 51 3728 9911

Email

Zamanigh@mums.ac.ir

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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Phone

+98 51 3845 2474

Email

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

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

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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**Person responsible for updating data****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

Street address

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