

Is surgical treatment of recurrent eye styes more or less effective when followed by bloodletting by medicinal leeches?

Submission date 09/01/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 24/05/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 03/06/2020	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Eye styes are a lump on the eyelid that have clinical similarity to the inflammation of sebaceous glands. Based on clinical observations made at Government Ayurveda College Hospital, Thiruvananthapuram, the recurrence of the disease is defined as the re-appearance of the abscess in the same eye within a period of two months, even after incision and drainage. As per Ayurveda philosophy, the involvement of blood impurity causes eye styes to recur and leech therapy can be used to treat blood vitiation. Hence incision and drainage and leech therapy were incorporated to manage recurrent eye styes.

This study aimed to find the combined effectiveness of incision and drainage followed by leech therapy in managing recurrence of eye styes.

Who can participate?

Patients aged between 10 and 50 years with recurrence of eye styes in the same eye within a two month period even after surgical treatment

What does the study involve?

After obtaining consent, patients were randomly allocated to either the study group or the control group. In the study group, surgical intervention (incision and drainage) was followed by leech therapy. In the control group, incision and drainage were performed. The follow up was arranged on 15th day, 45th day, 75th day, and 105th day after treatment.

What are the possible benefits and risks of participating?

No side effects were noticed throughout the study period.

Where is the study run from?

Department of Shalakyatantra, Govt. Ayurveda College Trivandrum Government Ayurveda College Hospital (India).

When is the study starting and how long is it expected to run for?
April 2013 to May 2015

Who is funding the study?
Government Ayurveda College Trivandrum (India)

Who is the main contact?
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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
0422.12/2013

Study information

Scientific Title
Comparing surgical treatment alone vs surgical treatment followed by bloodletting by medicinal leeches in the treatment of recurrent eye styes: a randomised controlled trial.

Study objectives

A study on the combined effectiveness of surgical intervention followed by blood letting by medicinal leeches in recurrent eye styes. Blood letting by medicinal leeches will be user friendly and will not negatively effect management of the disease state

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 22/04/2013, Institutional Ethical Committee of the Government Ayurveda College Trivandrum (Kerala, India; +91 (0)471 2460190), ref: IEC.0422.12/2013

Study design

Randomised control parallel open 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

Eye stye

Interventions

Patients diagnosed as having recurrent eye styes were selected from the outpatient department and admitted to the inpatient department of Shalakyatantra at the trial site. After obtaining consent, patients were randomly allocated into either the study group or control group using a block randomization method. In study group patients were treated with a surgical intervention, incision and draining, followed by leech therapy. The control group were treated with incision and draining only.

Study group-treatment protocol

Pre-operative procedure

1. Administering of herbal ghee (dose according to age) for one day, the first day. Two times along with porridge.
2. The inducing of mild sweating with leaves over the eye stye was advised for one day, the first day. Bathing in hot water was also advised.
3. The herbal powder, avipathi choornam (dose according to the age) was administered along with hot milk as a part of purgative therapy for one day, the second day

Procedure

1. Incision at pus point by surgical blade (No.12) and evacuation.

Post-operative procedure

1. Rub the wound with rock salt and honey

2. Wash the wound with lukewarm distilled water

3. Bandaging:

3.1. Eye bandage with honey and herbal ghee

3.2. 3rd day, re-bandage after pouring medicated water (herbal blend triphala kashaya) for 6 minutes over the eyelid while eye is closed

3.3. 5th day, bandage removed and advised to discharge on 6th day

4. Blood letting: para-surgical procedure on 7th day

Blood letting by medicinal leeches

A non-poisonous variety of leeches called kapila was selected for the procedure.

Preparation of the patient

The patient should be made to lie down. The whole face should be covered and except the eye where leeches are to be applied.

Preparation of leeches

The leeches should be grasped and a mixture of mustard and turmeric paste in water should be applied upon them and then for 48 minutes they should be kept in a vessel of water.

Application of leeches

Medium sized (0.5-1.5gm) medicinal leeches were made to suck from inner aspect of both eyelids at a room temperature 28 degrees Celsius. The leeches should be fully covered with fine wet cloth except for the mouth which should be left exposed. When the leech's mouth gets stuck to the site (eyelid) and its middle part becomes raised assuming the shape of a horseshoe it should be known that it is sucking well. In the study leeches were made to suck over the inner surface of both the upper and lower eyelids. When pricking pain or itching is felt by the patient at the site of application the leech should be removed. If it does not withdraw, rock salt should be sprinkled upon its mouth.

Removal of sucked blood from the leeches

When the leech has fallen away its body should be massaged with rice powder and its mouth by sesame oil and rock salt. Its hind part should then be held by the left hand in between the thumb and fingers and it should be slowly and gently squeezed from tail end to mouth by thumb and fingers of the right hand. When completely emptied the leech is left in a vessel of water and should move to and fro in search of food. If the leech which sinks into the water does not move after being left it should again be made to vomit properly until empty. The same leeches should not be used again for the next 7 days to protect them from blood intoxication.

Local treatment at the site of leech application

Wash the eye with the herbal blend triphala kashaya. After bleeding slows, apply an eye bandage using honey and herbal ghee. Bandage is to be removed on the next day followed by eye wash with the herbal blend triphala kashaya.

After the procedure patient was discharged from the hospital and three subsequent blood letting procedures were arranged on every 8th day.

Follow-up

Follow up was arranged on 15th day, 45th day, 75th day and 105th day.

Control group-treatment protocol

Pre-operative procedure:

1. Administering of herbal ghee (dose according to age) for one day, the first day. Two times along with porridge.
2. The inducing of mild sweating with leaves over the eye styte was advised for one day, the first day. Bathing in hot water was also advised.
3. The herbal powder, avipathi choornam (dose according to the age) was administered along with hot milk as a part of purgative therapy for one day, the second day

Procedure:

1. Incision at pus point by surgical blade (No.12) and evacuation

Post-operative procedure:

1. Rub the wound with rock salt and honey
2. Wash the wound with luke warm distilled water
3. Bandaging:
 - 3.1. Eye bandage with honey and herbal ghee
 - 3.2. 3rd day, re-bandage after pouring medicated water (herbal blend triphala kashaya) for 6 minutes over the eyelid while eye is closed
 - 3.3. 5th day, bandage removed and advised to discharge on 6th day

Follow-up:

Follow up was arranged on 15th day, 45th day, 75th day and 105th day

Intervention Type

Procedure/Surgery

Primary outcome measure

Stye recurrence was determined by interview at baseline, day 15, day 45, day 75, and day 105

Secondary outcome measures

1. Swelling was measured using the Vernier calliper at baseline, day 15, day 45, day 75 and day 105
2. Burning sensation was measured using the visual analogue scale at baseline, day 15, day 45, day 75 and day 105
3. Pain was measured using the visual analogue scale at baseline, day 15, day 45, day 75 and day 105

Overall study start date

22/04/2013

Completion date

07/05/2015

Eligibility

Key inclusion criteria

1. Aged 10 - 50 years
2. Recurrence of styne in the same eye within a two-month period, even after treatment with incision and drainage

Participant type(s)

Patient

Age group

Mixed

Sex

Both

Target number of participants

40 eyes (20 eyes in the study group and 20 eyes in the control group)

Total final enrolment

40

Key exclusion criteria

1. Bleeding disorders
2. Diabetes mellitus
3. Anaemia
4. Uncorrected refractive error
5. Patients undergoing anti-platelet drug therapy
6. Malignancy

Date of first enrolment

20/05/2013

Date of final enrolment

10/01/2015

Locations**Countries of recruitment**

India

Study participating centre

Government Ayurveda College Hospital

Department of Shalakyatantra

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Funder(s)

Funder type

Government

Funder Name

Government Ayurveda College Trivandrum

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

02/04/2019

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			03/06/2020	No	No