

Investigating different face-washing methods for reducing the chance of spreading the infection that causes trachoma

Submission date 12/03/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 17/04/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 23/04/2025	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Trachoma, a Neglected Tropical Disease (NTD), is the commonest infectious cause of blindness globally, affecting some of the world's poorest communities. Trachoma elimination requires implementation of the World Health Organization (WHO)-endorsed SAFE strategy: Surgery for trichiasis; Antibiotics to treat infection; Facial cleanliness and Environmental improvement to reduce transmission. Improving the evidence base for the "F" component of the SAFE strategy for trachoma elimination is highlighted as a critical action to reach 2030 targets in the WHO NTD Roadmap 2021–2030; the proposed research directly addresses that critical action. There is currently a lot of international momentum to understand better the "F" component of the SAFE strategy to improve both resource allocation and intervention effectiveness. This study is the first of its kind to explore whether and how face washing can remove *Chlamydia trachomatis* (Ct) bacteria from children's faces. The proposed study leverages collaborations formed during the Stronger-SAFE trial and builds on published pilot work conducted in Ethiopia in 2018. The aim of this study is to assess the effectiveness of different face cleansing protocols at removing *Chlamydia trachomatis* (Ct) bacteria and eye/nose secretions from the faces of children with active trachoma. The study will also assess how long it takes for Ct to build up again on children's faces after they are washed.

Who can participate?

Children aged 1–7 years with severe follicular and/or papillary inflammation and their caregivers

What does the study involve?

Programmatic trachoma survey data will be reviewed to identify high prevalence woredas (districts of Ethiopia). Participants will be identified through screening of children for clinical signs of severe trachoma in suspected high-prevalence communities of Ethiopia. Once parental consent has been obtained, the researchers will take a conjunctival (eye) swab to test for Ct infection, swab each child's face and hands for Ct and assess facial cleanliness. Recruited children will be randomly allocated into three equal groups: face washing with water only, face

washing with water and soap and face washing with a SuperTowel. Following face washing, each child's face and hands will be swabbed again for Ct. Swabbing will be repeated at regular intervals up to 8 hours.

What are the possible benefits and risks of participating?

This is a low-risk study and very few risks have been identified to taking part. There is a small risk of allergy or sensitivity to soap or SuperTowel products, but as the intervention only lasts 30 seconds a severe reaction is very unlikely. There is a risk of getting soap in the eye which can be sore, but discomfort would only be temporary.

Participants will receive a bar of soap at the end of the trial, in recognition of the wider role soap plays in hygienic behaviours. Participants with trachoma will receive antibiotic treatment. Those screened who either are not eligible or decline consent will also receive treatment. Participants may also receive a small token of appreciation (a pen, a football, etc). There are no other benefits to taking part.

Where is the study run from?

The study is a collaboration between the London School of Hygiene & Tropical Medicine (UK) and Berhane Public Health Consultancy (Ethiopia). Oromia Regional Health Bureau and Fred Hollows Foundation Ethiopia are also contributing to the study.

When is the study starting and how long is it expected to run for?

January 2019 to June 2023

Who is funding the study?

Reckitt Global Hygiene Institute

Who is the main contact?

1. Katie Greenland, katie.greenland@lshtm.ac.uk

2. Wondu Alemayehu, walemayehu@berhan-health.org

Contact information

Type(s)

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Additional identifiers**EudraCT/CTIS number**

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

LSHTM Ethics Reference 16470

Study information**Scientific Title**

The Face Washing Methods (FAWASH) trial: an open, parallel-group randomized controlled trial comparing face washing methods for the removal of Chlamydia trachomatis

Acronym

FAWASH

Study objectives

Face washing with water and soap will remove Chlamydia trachomatis from more children's faces than face washing with water alone.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Approved 02/02/2023, London School of Hygiene & Tropical Medicine Interventions Ethics Committee (Keppel Street, London, WC1E 7HT, UK; +44 (0)207 636 8638; ethics@lshtm.ac.uk), ref: 16470

2. Approved 26/01/2023, Ethiopian Food and Drug Authority (PO Box 5681, Addis Ababa, Ethiopia; +251 (0)552 414 123; regulatory@fmhaca.gov.et), ref: 02/25/33/01

3. Approved 22/07/2022; Ethiopia Ministry of Education National Health Research Ethics Committee (PO Box 1367, Arada sub-city, Addis Ababa, Ethiopia, +251 (0)11 155 3133; info@moe.gov.et), ref: 03/246/938/22

4. Approved 20/02/2023, Oromia Regional Health Bureau (PO Box 24341, Addis Ababa, Ethiopia; +251 (0)113 717 277; ohbhead@telecom.net.et), ref BF/UBT/V?H6/10002

Study design

Three-arm open parallel-group randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Community

Study type(s)

Prevention

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

Removal of Chlamydia trachomatis from the face of children aged 1-7 years with ocular C. trachomatis infection

Interventions

Participants are randomized to one of the three arms in a 1:1:1 ratio at the point of wash using a random number generator:

Protocol A: Caregiver delivers a 30-second face wash with water only

Protocol B: Caregiver delivers a 30-second face wash with water and soap

Protocol C: Caregiver delivers a 15-20 second face wash with a damp SuperTowel

In all protocols caregivers are instructed to wash their children's faces in a natural manner, but take care to reach all areas of the face.

Intervention Type

Behavioural

Primary outcome measure

Relative reduction in the proportion of participants without Chlamydia trachomatis detected on faces by real-time PCR immediately following face washing with soap and water, compared with the face washing with water only group

Secondary outcome measures

1. Relative reduction in the proportion of participants without Chlamydia trachomatis detected on faces by real-time PCR immediately following face wiping with the SuperTowel, as compared to the water-only arm
2. Difference between arms in the proportion of participants without ocular or dry nasal discharge on faces, measured by consensus observation, immediately following washing/wiping protocol

3. Difference between arms in the mean load of Chlamydia trachomatis on faces, measured by real-time PCR, immediately following the washing/wiping protocol
4. Difference between arms in the proportion of participants without Chlamydia trachomatis (by real-time PCR)/ocular and nasal discharge (by consensus observation) on faces at 1, 2, 4, 6 and 8 hours following the washing/wiping protocol
5. Mean increase in load of Chlamydia trachomatis, measured by real-time PCR, on faces at 1, 2, 4, 6 and 8 hours following protocol

Overall study start date

30/01/2019

Completion date

30/06/2023

Eligibility

Key inclusion criteria

1. Parental consent to take part
2. Participant assent to take part
3. Severe conjunctival inflammation (F3 and/or P3)
4. Aged 1-7 years residents of Oromia State, Ethiopia
5. Availability for the study period (8 hours)

Participant type(s)

Healthy volunteer

Age group

Child

Lower age limit

1 Years

Upper age limit

7 Years

Sex

Both

Target number of participants

470

Key exclusion criteria

1. Known allergy to study materials
2. Significant facial and/or ocular injury or pathology

Date of first enrolment

20/03/2023

Date of final enrolment

30/06/2023

Locations

Countries of recruitment

Ethiopia

Study participating centre

Arsi Zone, Oromia Region

Ethiopia

Arsi Zone

Sponsor information

Organisation

London School of Hygiene & Tropical Medicine

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Sponsor type

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Funder(s)

Funder type

Research organisation

Funder Name

Reckitt Global Hygiene Institute

Results and Publications

Publication and dissemination plan

Scientific results will be published in open access peer-reviewed journals and presented at relevant international conferences. Results will also be disseminated to trial stakeholders and the wider trachoma control community.

Intention to publish date

31/12/2025

Individual participant data (IPD) sharing plan

The datasets generated during and analysed during the current study will be available upon request from Katie Greenland (katie.greenland@lshtm.ac.uk) upon study publication.

Added 11/06/2024:

Fully anonymised data will be deposited in a public repository following publication.

IPD sharing plan summary

Stored in publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 3.1	09/01/2023	11/06/2024	No	No