ISRCTN12814010 https://doi.org/10.1186/ISRCTN12814010

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

Registration date
17/04/2023

Overall study status
Completed

Last Edited
12/01/2026

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Prevention

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(s)
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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
1 years

Upper age limit
7 years

Sex
All

Total final enrolment
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

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Research organisation

Funder Name
Reckitt Global Hygiene Institute

Results and Publications

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
Available on request, Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		09/01/2026	12/01/2026	Yes	No
Protocol file	version 3.1	09/01/2023	11/06/2024	No	No