

Evaluation of N-acetyl cysteine mouth wash as a new treatment approach for gingivitis

Submission date 22/01/2017	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 22/02/2017	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 27/11/2020	Condition category Oral Health	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Gingivitis is a disease that causes inflammation (swelling) of the gums. Symptoms include gums that are red, swollen and bleeding. One of the main causes is dental plaque (sticky, colourless film of bacteria and sugars that forms on teeth). It can be hard to remove plaque so using mouthwash is recommended to fight plaque and to prevent gingivitis. Mouthwashes that include chlorhexidine (CHX) (an ingredient that is used to sterilize and disinfect) are the most widely used. However, there are side effects of this kind of mouthwash, such as mouth ulcers (small holes inside in the mouth) and allergic reactions (i.e. itching, hives, and swelling). Mouthwashes that include N-acetyl cysteine (NAC) (a more natural ingredient that prevents the build-up of plaque) have been suggested as alternatives but they need to be tested for effectiveness. This study will be conducted to evaluate and compare the effects of an NAC mouthwash against CHX in prevention and treatment of plaque-induced gingivitis.

Who can participate?

Adults aged 18-28

What does the study involve?

This study has two phases. In the first phase of the study, participants are randomly allocated to one of three groups. Participants are instructed to not brush their teeth during the study. Those in the first group use an N-acetyl cysteine mouthwash twice daily for one minute for 21 days. Those in the second group use CHX mouthwash to use twice daily for one minute for 21 days. Those in the last group use water twice daily for one minute for 21 days. After this phase, participants in the last group are then allocated to one of two groups. Those in the first group use NAC mouthwash twice daily for one minute for 14 days. Those in the second group use CHX twice daily for one minute for 14 days. Participants in the first phase are followed up for dental examinations and bacteria samples at 7, 14, and 21 days after completing the treatment. Participants in the second phases have addition follow up 28 and 35 days after their treatment.

What are the possible benefits and risks of participating?

There are no direct benefits or risks to participants.

Where is the study run from?
University of Science and Technology, Sana'a (Yemen)

When is the study starting and how long is it expected to run for?
December 2016 to January 2018.

Who is funding the study?
University of Science and Technology, Sana'a (Yemen)

Who is the main contact?
Dr. Ahlam Al-kamel
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
2016/20

Study information

Scientific Title
Efficacy of N-acetyl cysteine mouth wash in the prevention and treatment of experimental gingivitis: A randomised clinical trial

Study objectives
Null hypothesis:
N-acetyl cysteine is as effective as chlorhexidine in treating experimental gingivitis.

Alternative hypothesis:
N-acetyl cysteine is more effective than chlorhexidine in treating experimental gingivitis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Research Ethics Committee University of Sciences and Technology, 20/12/2016, ref: 2016/20

Primary study design

Interventional

Study design

Stage 1: Single-centre three-arm double-blind randomised controlled trial

Stage 2: Single-centre double-blind randomised parallel trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Gingivitis

Interventions

This study has two phases. Participant are randomly divided to three groups by drawing sealed and opaque envelopes containing the codes (A), (B), (C). The induction of experimental gingivitis will be done by instructing the participant not to brush their teeth during the period of study. This study will consist of two stages:

Stage One (Preventative):

This is a preventive stage in which the mouthwash is examined to prove its effect to prevent experimental gingivitis. They are also instructed not to drink, eat or rinse for thirty minutes after mouth washing. This stage is 21 days long. During this stage the participants are allocated to one of three groups:

Group (A): 20 healthy gingiva participants, who use 10 ml of 0.25% N-acetyl cysteine solution as mouth wash, twice daily for one minute (test group)

Group (B): 20 healthy gingiva participants, who use 10 ml of 0.2% (CHX) twice daily for one minute (positive control group)

Group (C): 20 healthy gingiva participants, who use 10 ml of water or placebo twice daily for one minute (negative control group)

Stage Two (Treatment):

After preventive stage, the placebo group (group C) are allocated to one of two groups in the treatment stage randomly by drawing sealed and opaque envelopes containing the codes (C1) and (C2):

Group (C1): 10 experimental plaque-induced gingivitis participants, who use 10 ml of 0.25% (NAC) solution as mouthwash, twice daily for one minute (test group).

Group (C2): 10 experimental plaque-induced gingivitis participants, who use 10 ml of 0.2% (CHX) twice daily for one minute (control group).

The treatment stage includes CHX and the experimental new mouthwash NAC mouthwash used to treat the experimental plaque-induced gingivitis. Participants are instructed not to drink, eat or rinse for thirty minutes after mouth washing. A comparison between the therapeutic effects of both mouthwashes is done. This stage lasts 14 days.

Follow-up includes visits for intra-oral clinical examination and bacterial sampling from the participants. The follow-up visits for groups A, B and C in stage one preventive stage is at

baseline and 7, 14 and 21 days of using mouth wash. After the completion of stage one (21 days), group C will be divided into two groups C1 and C2 at stage two (Treatment stage). The follow up in this stage will be at day 28 and 35.

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

N-acetyl cysteine

Primary outcome(s)

Bacteria in sub-gingival plaque is measured using bacteria samples from the participants analyzed using DNA sequencing at baseline and day 21 and 35.

Key secondary outcome(s)

For the preventative and treatment stages:

1. Plaque is measured using an index scoring system from 0-3 at baseline and at day 7, 14, 21, 28 and 35
2. Gingival index is measured using an index scoring system from 0-3 at baseline and at day 7, 14, 21, 28 and 35
3. Papilla bleeding is measured using an index scoring system from 1-4 at baseline and at day 7, 14, 21, 28 and 35

Completion date

01/01/2018

Eligibility**Key inclusion criteria**

1. Healthy gingiva with no evidence of periodontitis
2. Male and females aged between 18 to 28
3. Willing to participate and comply with the objectives of the study

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Total final enrolment

60

Key exclusion criteria

1. Regular users of antiplaque rinses or the use of oral rinses for 30 days before baseline
2. Antibiotics intake within the previous 2 months
3. Smokers
4. Pregnancy or lactation
5. Systemic diseases or long term medications that influencing gingival conditions
6. Orthodontic appliance
7. Presence of detectable increased attachment loss
8. Chewing khat (flowering plant native to the Horn of Africa and the Arabian Peninsula)

Date of first enrolment

01/03/2017

Date of final enrolment

30/05/2017

Locations**Countries of recruitment**

Yemen

Study participating centre

University of Science and Technology

Sixty Street

Sana'a

Yemen

13064-15201

Sponsor information**Organisation**

University of Science and Technology

ROR

<https://ror.org/05bj7sh33>

Funder(s)**Funder type**

University/education

Funder Name

University of Science and Technology - Yemen

Results and Publications

Individual participant data (IPD) sharing plan

The current 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?
Results article	results	01/10/2019		Yes	No