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

Submission date
22/01/2017

Recruitment status
No longer recruiting

Registration date
22/02/2017

Overall study status
Completed

Last Edited
27/11/2020

Condition category
Oral Health

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
a.alkamel@ust.edu

Contact information

Type(s)
Scientific

Contact name
Dr Ahlam Al-kamel

Contact details
University of Science and Technology
Sanaa Rd,
Taizz
Sana'a
Yemen
13064- 15201
+967 775 532 303
a.alkamel@ust.edu

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Stage 1: Single-centre three-arm double-blind randomised controlled trial
Stage 2: Single-centre double-blind randomised parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
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

Overall study start date
01/12/2016

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

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

Sponsor details
Sanaa Road
Taizz
Sana'a
Yemen
13064- 15201
+967 01 227 072
info@ust.edu

Sponsor type
University/education

Website
www.ust.edu

ROR
https://ror.org/05bj7sh33

Funder(s)

Funder type
University/education

Funder Name
University of Science and Technology - Yemen

Results and Publications

Publication and dissemination plan
Planned publication in a high impact journal.

Intention to publish date
01/01/2019

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