ISRCTN38327678 https://doi.org/10.1186/ISRCTN38327678

The efficacy of honey mouth-rinse on the intra-oral flora

Submission date	Recruitment status	[ ] Prospectively registered
19/12/2019	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
17/01/2020	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
17/01/2020	Oral Health	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Mouth rinses are considered as an essential mean of oral hygiene, but due to the side effects of its chemical ingredients the search for a natural alternative had begun. Honey is one of these alternatives and has been long known for its antimicrobial properties.
Aims: This study aimed to evaluate the efficacy of Syrian Honey mouth rinse on salivary flora in comparison with Chlorhexidine 0.12% mouth rinse.

Who can participate?
Healthy adults with good oral hygiene.

What does the study involve?
Participants are randomly allocated to use the products, Honey mouth rinse, Chlorhexidine 0.12% mouth rinse, or placebo, in a different order. Participants use each product once for 30 seconds, after seven days they use the next product etc. One minute and 30 minutes after using the product a saliva sample will be collected.

What are the possible benefits and risks of participating?
Possible benefit is finding an alternative for the chemical mouth rinse by using a certain concentration of honey. There are no risks from participating at all, all three groups of treatment used approved materials which causes no harms for patients, groups A commercial chlorhexidine, group B honey mouth rinse, group C distilled water.

Where is the study run from?
Damascus University - Faculty of Dental Medicine, Syria

When is the study starting and how long is it expected to run for?
January 2019 to March 2019

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
18-1728

Study information

Scientific Title
Randomized controlled trial to evaluate the efficacy of honey mouth-rinse on the intra-oral flora: a cross-over study

Study objectives
The honey mouth rinse has an antimicrobial efficacy on the intra oral flora

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 16/04/2013, Ethical Committee of the Faculty of Dental Medicine (Damascus University, Damascus, Syria; +963 113341864; manager@hcsr.gov.sy), ref: none

Study design
Interventional randomised cross over trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Intra oral flora

Interventions
The effectiveness of Syrian honey mouth rinse on salivary floral bacteria was investigated at the inhibitory concentration suitable for use as a mouth rinse define by diffusion method on Muller-Hinton agar to reach the suitable concentration which is found to be 50%. The disinfecting effect of this 50% solution was studied in a triple blinded study in comparison with Chlorhexidine 0.12%, and distilled water as control. Each participant used the three solutions once for 30 sec 7 days apart. Then the saliva colony forming unit (CFU) count was measured after rinsing by 1 and 30 min.

Group A: honey mouth rinse 50%.
Group B: chlorhexidine 0.12%
Group C: control (distilled water)

Randomization:
The researcher prepared special cards numbered from (1-40) and each patient took one card randomly from a black box, each card had a letter (A,B OR C). each letter refers to a certain treatment group, nether the researcher, the volunteer or the statistician know what the letter refers to until the end of the data analysis.

Intervention Type
Supplement

Primary outcome measure

The colony forming unit counts (CFU) measured using saliva samples collected from each patient on three different timepoints (before the test, after one minute of the mouth rinse, after 30 minutes of mouth rinse)

Secondary outcome measures
Oral health index collected using oral examination and with UNC15 probe (university of North Carolina). Oral data collected from each patient on three different timepoints (before the test, after one minute of the mouth rinse, after 30 minutes of mouth rinse).
1. Plaque index (PI)
2. Gingival index (GI)
3. Decayed, missing, filled teeth index

Overall study start date
01/09/2018

Completion date
01/03/2019

Eligibility

Key inclusion criteria
Healthy volunteers with good oral hygiene

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
40

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/01/2019

Date of final enrolment
01/02/2019

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University - Faculty of Dental Medicine
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Sponsor information

Organisation
Damascus University

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Sponsor type
University/education

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ROR
https://ror.org/03m098d13

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan

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

Intention to publish date
01/02/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary
Available on request