

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

<b>Submission date</b> 19/12/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 17/01/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 17/01/2020	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?  
Dr Mhd Bahaa Aldin Alhaffar  
bhaa.alhaffar@gmail.com

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Mhd Bahaa Aldin Alhaffar

**ORCID ID**  
<https://orcid.org/0000-0002-9147-189X>

**Contact details**  
Damascus university  
Faculty of dental medicine  
Department of periodontology  
Damascus  
Syria  
00000  
+963 932985177  
bhaa.alhaffar@gmail.com

## Additional identifiers

**Protocol serial number**  
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

## Study type(s)

Prevention

## 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(s)

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)

## Key secondary outcome(s)

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

## Completion date

01/03/2019

## Eligibility

### Key inclusion criteria

Healthy volunteers with good oral hygiene

**Participant type(s)**

Healthy volunteer

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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**

Almazzah St.

Damascus

Syria

00000

## **Sponsor information**

**Organisation**

Damascus University

**ROR**

<https://ror.org/03m098d13>

## **Funder(s)**

### **Funder type**

Other

### **Funder Name**

Investigator initiated and funded

## **Results and Publications**

### **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