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# Effect of Gum Arabic on chronic gingivitis

**Submission date**
07/09/2016

**Recruitment status**
No longer recruiting

**Registration date**
02/10/2016

**Overall study status**
Completed

**Last Edited**
13/09/2022

**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
Gum Arabic (GA) is a natural product which has been used for centuries as a traditional oral hygiene substance in Arabian and African countries. Many studies have been run that support the potential activity of GA as an antiplaque agent; it is thought that it may act to prevent dental plaque formation. The present study was designed to test the effect of GA on chronic gingivitis, to assess the effect of introducing GA to a group of patients to see whether it reduces plague formation and gingivitis and compare the progress of gingivitis between a group who are given GA and a group that is given a placebo (dummy) gum. It also wants to test whether the presence of a protein called Interleukin 1 beta (IL-1β) can predict whether gum (periodontal) disease is progressing.

Who can participate?
Adults with mild to moderate gingivitis.

What does the study involve?
Participants are randomly allocated to one of two groups. After brushing their teeth, those in group 1 are asked to apply half a teaspoon of GA gently by finger to the border line between teeth and gums - the so-called dentogingival area – for around and hour and then leave it for five minutes before washing with water. Similarly, after brushing their teeth, participants in group 2 are asked to apply half a teaspoon of placebo powder gently by finger to the dentogingival area for around and hour and then leave it for five minutes before washing with water. All participants in both groups are asked to otherwise follow their usual regular oral hygiene habits. A gum disease assessment is carried out for all participants one month later and repeated after two months.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Khartoum Dental Teaching Hospital (Sudan)

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

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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# Contact information

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
905661087

# Study information

### Scientific Title
Clinical and immunological effect of Gum Arabic in patients with chronic gingivitis in Khartoum Dental Teaching Hospital, in Khartoum state in Sudan: randomised controlled trial

### Study objectives
General objectives:
To evaluate the effect of Gum Arabic (GA) on chronic gingivitis.

Specific objectives:
1. To assess the periodontal health status (GI, PI) of a population of the study at Khartoum Dental Teaching Hospital (KDTH)
2. To assess the effect of introducing GA to a group of patients with gingivitis at baseline on the following clinical indicators: PI, GI and immunological indicator (IL-1 β)
3. To compare the progress of gingivitis between a group who received GA versus a group who received placebo treatment
4. To assess the ability of IL-1β as predictor of periodontal disease progression

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Federal Ministry of Health - National Medicines and Poisons Board review board, 25/08/2016

### Study design
Double blinded, parallel, placebo, randomized clinical control trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

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

### Health condition(s) or problem(s) studied

Chronic gingivitis

## Interventions

Before the start of the clinical examination, all the participants who are eligible and accepted the invitation to participate will have the objectives and the methodology of the study explained. All participates will be asked to sign a consent form outlining the goals and the procedures of the clinical trial. The acceptance from the ethical committees will be sought from the concerned bodies at the KDTH, Sudan Medical Specialization Board (SMSB) and the Federal Ministry of Health (FMOH).

Randomization and Allocation: The participates will be assigned to one of the two groups, group A (intervention group) or group B (placebo group), by restricted randomization (blocking).

1. Step one (baseline):
Clinical examination will be carried out at baseline.
Before starting the clinical assessment, each participant will be asked to gargle with saline 10 ml to remove any food debris and materia alba. Under identical conditions, an oral examination in a dental chair and light to examine the dental and periodontal status using a dental mirror and a graduated William's periodontal probe will be undertaken and scored by the candidate.
In case of exposure of blindness to the examiner (to know that the patient is assigned to the intervention group or placebo group), another dentist will undergo the follow-up clinical examinations. This clinical examiner will be calibrated to the principal examiner, and the calibration will be tested using the kappa test.
At baseline all the participants will receive thorough and meticulous scaling and polishing to remove all existing plaque, calculus deposits and extrinsic stains (will be performed by the candidate).

Each participant will then be randomly assigned to one of the two groups by the assistant:

Group 1: Participants are asked to apply half of teaspoon quantity of the Gum Arabic (GA) formula gently by finger to the dentogingival area for about an hour following tooth brushing and to leave application for five minutes before washing with normal water. Regular use in the morning and evening after one hour from regular brushing will be advised.
Group 2: Participants will be asked to apply half of teaspoon quantity of a placebo formula gently by finger to the dentogingival area for about an hour following tooth brushing and to leave application for five minutes before washing with normal water. Regular use in the morning and evening after one hour from regular brushing will be advised.

All participants will be asked to maintain their regular oral hygiene habits. Also, no prophylaxis will be carried out preceding the onset of the study on the participants. All of the participants will receive the sealed containers (150 g), and they are also blinded to the type of the formula (either GA or placebo). They will be instructed by the assistant not to share any information with the examiner to ensure blindness.

2. Step two (after one month):
The periodontal status of all of the participants will be assessed (by the candidate) using the same clinical parameters (GI, PI) and GCF also will be collected by the same tools. All of the participants will be referred to the assistant to give them the remaining of the formulas (300 g) for rest of the study.

3. Step three (after two months):
All of the procedures which have been conducted at the fourth week will be repeated and final periodontal assessment will be carried out.

### Intervention Type
Other

### Primary outcome measure
Severity of plaque build-up, measured by Plaque index of Sillness and Loe

Three measurements are taken during the study period: Baseline, after one month, after two months.

### Secondary outcome measures
1. Severity of gingivitis, assessed using the Gingival Index of Loe and Sillness
2. Content of gingival crevicular fluid (GCF)

Three measurements are taken during the study period: Baseline, after one month, after two months.

### Overall study start date
15/10/2016

### Completion date
15/12/2016

## Eligibility

### Key inclusion criteria
1. Patients diagnosed with generalized mild-moderate chronic plaque-induced gingivitis
2. At least twenty natural teeth must be present in the oral cavity
3. No history of periodontal therapy or previous use of antibiotics or anti-inflammatory drugs within the preceding six months will be included in the study
4. Patient fulfilling the clinical and radiographic criteria of the gingival index (Löe and Silness) >1, plaque index (Silness and Löe) >1, pocket probing depth <3 mm, clinical attachment loss = 0, with no evidence of radiographic bone loss

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
Sample size calculation: Sample size was calculated using openepi.com, using the equation for RCT, assuming a two sided confidence interval of 95%, power of 80%, ration of exposed to

unexposed in the sample of 1:1, and a percentage of 35% of the exposed to have an improved GI and PI by the end of the study. Total sample size (Kelsey calculation) of 56, 28 in each group. To overcome withdrawal of patients we raise the sample size to 60.

### Total final enrolment
60

### Key exclusion criteria
1. Patients with known allergies to the constituents of the Gum Arabic formulation
2. Hematological disorders or other systemic illness
3. Pregnant and lactating females
4. Patients undergoing orthodontic treatment
5. Patients with smoking habits

### Date of first enrolment
15/10/2016

### Date of final enrolment
15/12/2016

## Locations

### Countries of recruitment
Sudan

### Study participating centre
**Khartoum Dental Teaching Hospital**
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## Sponsor information

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Sudan Medical Specialization Board.

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### Sponsor type

University/education

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**ROR**
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# Funder(s)

**Funder type**
Other

**Funder Name**
Investigator initiated and funded

# Results and Publications

**Publication and dissemination plan**
The authors intend to publish the article with the results. The target journal is yet to be confirmed.

**Intention to publish date**
15/12/2017

**Individual participant data (IPD) sharing plan**
Not provided at time of registration

**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 | | 13/06/2022 | 13/09/2022 | Yes | No |