

# Comparison of two mouth rinses (Triphala and Listerine) in patients undergoing fixed orthodontic therapy

<b>Submission date</b> 04/04/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 19/04/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 18/04/2018	<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

The aim of this study is to assess the effect of 0.6% Triphala mouth rinse as compared to Listerine on gingival (gum) health in patients undergoing fixed orthodontic (brace) treatment.

### Who can participate?

Patients aged 18-30 undergoing fixed orthodontic treatment with signs of gum inflammation

### What does the study involve?

Participants are randomly allocated into two groups to use either 0.6% Triphala or Listerine mouth rinse twice daily. Both groups are assessed for gum inflammation, plaque and oral hygiene after 7, 14 and 30 days.

### What are the possible benefits and risks of participating?

Using Listerine may reduce gum inflammation and plaque build-up. Possible risks include allergy or mild burning sensation due to the alcohol content. Triphala is a herbal product, widely used in Ayurvedic practice. In this study it is used as an oral rinse at a very low concentration and the risks associated with it are with overdose of a systemically administered form.

### Where is the study run from?

Amrita School of Dentistry, Amrita Vishwavidyapeetham (India)

### When is the study starting and how long is it expected to run for?

September 2015 to November 2017

### Who is funding the study?

Investigator initiated and funded

### Who is the main contact?

Dr Roshni Nair  
dr.roshninair@yahoo.in

# Contact information

## Type(s)

Scientific

## Contact name

Dr Roshni Nair

## Contact details

Department of Periodontics

Amrita School of Dentistry

AIMS Cochin

Cochin

India

682041

+91 (0)9845866696

dr.roshninair@yahoo.in

# Additional identifiers

## Protocol serial number

004

# Study information

## Scientific Title

Comparing efficacy of 0.6% Triphala with Listerine mouth rinse on gingival health during fixed orthodontic therapy

## Study objectives

To assess the effect of 0.6% Triphala mouth rinse as compared to Listerine on gingival health in patients undergoing fixed orthodontic therapy at an interval of 7 days, 14 days and 30 days.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Thesis Protocol Review Committee (Scientific, Ethical, Financial), 15/03/2016, ref/004/TPRC/2016

## Study design

Interventional single-centre single-blind parallel study

## Primary study design

Interventional

## Study type(s)

Treatment

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

Gingival inflammation and associated enlargement, plaque commonly seen in patients undergoing fixed orthodontic treatment

### **Interventions**

Patients were assigned to one of two groups by block randomization, single blind masking:

1. Reference arm: Listerine mouth rinse
2. Active arm: 0.6% Triphala mouth rinse

Both groups are assessed on clinical parameters (baseline assessment: gingival status, plaque score and oral hygiene score) followed by removal of existing dental hard and soft deposits by supragingival scaling. Patients in each group get the respective mouth rinse and rinse twice daily with 20 ml of the prescribed mouth rinse. Reassessment of the clinical parameters is carried out at 7, 14 and 30 days. Total duration of treatment 30 days.

### **Intervention Type**

Other

### **Primary outcome(s)**

Gum inflammation and associated gingival enlargement, assessed using Modified Gingival Index and Seymour Gingival Enlargement Index at baseline, 7, 14 and 30 days

### **Key secondary outcome(s)**

Plaque build up and oral hygiene status, assessed using Plaque Index and Simplified Oral Hygiene Index at baseline, 7, 14 and 30 days

### **Completion date**

04/11/2017

## **Eligibility**

### **Key inclusion criteria**

1. Age 18-30 years
2. Minimum of 20 teeth
3. Patients undergoing fixed orthodontic therapy with initial teeth alignment completed
4. Good general health - absence of any systemic illness
5. Gingival enlargement grade 1 or 2 (bokenkamp)
6. Gingival index above 2 (Modified Gingival Index by Lobene)

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

**Upper age limit**

30 years

**Sex**

All

**Key exclusion criteria**

1. Known hypersensitivity to the mouth rinses under study
2. Active periodontitis
3. Hard and soft tissue tumours
4. Oral red and white lesions
5. Antibiotic therapy in past 30 days
6. Use of mouthwash in the last 3 months
7. Medications with an effect on oral tissues
8. Habits: smoking, tobacco/paan chewing

**Date of first enrolment**

20/06/2016

**Date of final enrolment**

03/10/2017

**Locations****Countries of recruitment**

India

**Study participating centre**

Amrita School of Dentistry, Amrita Vishwavidyapeetham

Cochin

India

682041

**Sponsor information****Organisation**

Amrita School of Dentistry

**ROR**

<https://ror.org/03am10p12>

**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/will be available upon request from Dr Roshni Nair (dr.roshninair@yahoo.in).

**IPD sharing plan summary**

Available on request