

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

Submission date 04/04/2018	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 19/04/2018	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 18/04/2018	Condition category Oral Health	☐ Individual participant data ☐ 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
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Contact information

Type(s)

Scientific

Contact name

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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

Primary study design

Interventional

Study design

Interventional single-centre single-blind parallel study

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

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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