ISRCTN76770396 https://doi.org/10.1186/ISRCTN76770396

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

Submission date
04/04/2018

Recruitment status
No longer recruiting

Registration date
19/04/2018

Overall study status
Completed

Last Edited
18/04/2018

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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
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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised parallel 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 patient information sheet

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

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

Overall study start date
12/09/2015

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
30 Years

Sex
Both

Target number of participants
Two groups with 17 patients each

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

Sponsor details
Amrita Institute of Medical Science and Research Centre
Cochin
India
682041

Sponsor type
University/education

ROR
https://ror.org/03am10p12

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Study protocol can be available on request. Planned publication of the results in a high impact peer reviewed journal.

Intention to publish date

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