ISRCTN26530238 https://doi.org/10.1186/ISRCTN26530238

Antiplaque and antigingivitis effect of lippia sidoides

Submission date 11/07/2008	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 12/09/2008	**Overall study status** Completed	
Last Edited 12/09/2008	**Condition category** Oral Health	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Antiplaque and antigingivitis effect of lippia sidoides: A double-blind clinical study in humans

Study objectives
Gingivitis is a chronic inflammation of gingival tissues and is one of the most frequent periodontal diseases, affecting more than 90% of the population, regardless of age, sex or race.

Brazilian epidemiologic studies show a high prevalence of gingival inflammation, ranging from 74% to 100%, although the individual percentages of gingival bleeding reported by the media vary from 28% to 35%. The clinical signs of this disease are bleeding upon probing, plaque accumulation and pain.

This randomised controlled trial evaluated the antiplaque and antigingivitis effect of lippia sidoides (LS).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee (Comitê de Ética em Pesquisa, Coética), University of Fortaleza (UNIFOR). Data of approval: 25/07/2005 (ref: 205/2005)

Study design
Randomised, double-blind, placebo-controlled, cross-over study

Primary study design
Interventional

Study type(s)
Prevention

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

Interventions
Preparation of experimental gel: The essential oil of LS was extracted by steam distillation. Initially, 1 ml of essential oil was diluted in 9 ml of ethylic alcohol (1:9), preparing a 10% mixture. 50 g of carboxymethylcellulose was added to the LS infusion (1,000 ml) and the mixture was kept boiling until its complete dissolution to obtain the 10% gel concentration. A glycerin /ethanol mixture (50 ml: 50 ml) was added and the solution was vigorously stirred for 15 minutes until gel formation. A very small amount of menthol (flavouring) and conserving agent were added. The control gel had the same formulation except for the LS extract.

Twenty-six healthy volunteers (13 female and 13 male aged 19 to 25 years) were enrolled in this randomised, double-blind, cross-over study. The trial consisted of a pre-experimental phase and 2 experimental phases of 21 days each with a 1-month washout interval between them. To standardise the groups, the participants were submitted to a meticulous evaluation (pre-experimental phase) to score the plaque index (PLI), gingival index (GI) and the bleeding index (BI) of each tooth. All teeth of each subject were polished and flossed by the examiner to eliminate dental plaque remnants. The importance of oral hygiene was strongly reinforced.

Thirty days after the initial phase, the participants were randomly assigned to 2 groups (experimental phase). On day 0 of both experimental periods, PLI, GI and BI were recorded. A personal "kit" containing a toothshield, a tube with 90 g of control or test gel and a commercial dentifrice with no anti-inflammatory properties (Sorriso®) was given to all participants. During each 21-day experimental period, the participants were instructed to apply the gel onto the experimental teeth and leave for at least one minute, 3 times a day. The participants were asked to refrain from brushing the test quadrant, while the other teeth were normally brushed 3 times

a day using a commercial dentifrice. In addition to verbal instructions, the participants were given written recommendations to follow at home. On the last day of each period (21st day), the indexes were recorded and the teeth were polished with pumice.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The indexes (plaque index, gingival index and bleeding index) were recorded on the mesiobuccal, buccal, distobuccal, mesiolingual, lingual and distolingual surfaces of the experimental teeth and their mean scores were calculated. Then, mean scores for the 4 experimental teeth in each participant were calculated to determine the mean index score for the individual. Intra-examiner agreement for all indexes was calculated by repeating the measurements in 10 participants. Timepoints of assessment: Baseline and at the end of each of the two 21-day experimental phases.

Key secondary outcome(s))
Adverse effects, such as abscess, ulcerations and allergic reactions. The patients will be submitted to weekly evaluations for the observation of side effects within a maximum period of 21 days.

Completion date
30/11/2005

Eligibility

Key inclusion criteria
All subjects (both males and females, aged 19 to 25 years) had at least 20 natural teeth, 4 of which were posterior teeth in the lower left quadrant (experimental teeth)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Medical disorders
2. Under antimicrobial therapy
3. Smokers
4. Pregnant women

5. Individuals presenting a probing depth >3 mm associated with any mandibular teeth
6. Subjects with retentive factors of dental plaque, such as carious cavity and excess restoration in the test area

Date of first enrolment
01/08/2005

Date of final enrolment
30/11/2005

Locations

Countries of recruitment
Brazil

Study participating centre
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Sponsor information

Organisation
University of Fortaleza (Brazil)

ROR
https://ror.org/02ynbzc81

Funder(s)

Funder type
University/education

Funder Name
University of Fortaleza (UNIFOR) (Brazil)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration