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Evaluation of the efficacy and tolerance of a throat spray based on essential oil of Cymbopogon giganteus

Submission date
03/02/2023

Recruitment status
No longer recruiting

Registration date
11/03/2023

Overall study status
Completed

Last Edited
22/10/2024

Condition category
Signs and Symptoms

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Cymbopogon giganteus essential oil has long been used in traditional medicine to treat various respiratory conditions, including sore throat. To date, no modern formulation of this essential oil is available to treat sore throat. The objective of this study is therefore to evaluate the effectiveness and safety of use of a formulation of this oil in the form of a mouth spray in order to treat sore throat.

Who can participate?
137 volunteer participants, men and women, aged 18 to 65 years, who came for consultation at the CHDZ SURULERE in Cotonou, having been diagnosed with sore throat, will be recruited.

What does the study involve?
After signing the free and informed consent, they will be given the spray and the use and treatment regimen will be explained to them. They will be followed on an outpatient basis. Every day, we will call them to find out about their state of health and the adverse effects they may have had. On the 4th day, they will be reviewed and examined at the health center to assess efficacy and tolerance. In case of signs of aggravation, they will be immediately treated according to local standards. In case of improvement, they will continue the treatment until the 7th day. We will see them again on the 8th day for a final exit exam.

What are the possible benefits and risks of participating?
The advantage of participating in this study is their contribution to the development of local herbal medicines. the potential downside is that they will be followed on an outpatient basis, but the entire research team is informed and ready to support them in the event of serious adverse effects.

Where is the study run from?
Hospital and University Center of SURU-LERE area of Cotonou (Benin)

When is the study starting and how long is it expected to run for?
May 2022 to August 2023

Who is funding the study?
Pharmacy Training and Research Unit of the Faculty of Health Sciences of the University of Abomey-Calavi (Benin)

Who is the main contact?
Prof Habib Ganfon, hganfon@yahoo.fr

Contact information

Type(s)
Principal investigator

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
phyto/essaiclin 001/22

Study information

Scientific Title
Evaluation of the efficacy and tolerance of a throat spray based on essential oil of Cymbopogon giganteus on sore throat at the Hospital and University Center of SURU-LERE area of Cotonou

Study objectives
Mouthwash based on Cymbopogon giganteus essential oil is effective and well tolerated for treating sore throat

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/12/2022, Research Ethics Committee of the ISBA (Institute of Applied Bio-medical Sciences, 01 B.P., COTONOU, République du Bénin; +229 21 30 55 65; isba@intnet.bj), ref: 157

Study design
Prospective interventional non randomized

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Sore throat

Interventions
Participants will be treated with the traditional plant preparation as mouthwash for 7 days

Intervention Type
Supplement

Primary outcome(s)
Clinical signs of sore throat at baseline and 3 days measured by the treating physician:
1. Throat pain at the level of the oropharynx
2. Fever
3. Redness of the oropharynx
4. Oropharyngeal exudate
5. Hypertrophy of the tonsil
6. Lymphoid formation on the pharyngo-posterior wall
7. Cervical adenopathy

Key secondary outcome(s))
1. Clinical signs of sore throat at 7 days measured by the treating physician
2. Tolerance of the throat spray measured by patient report at 7 days

Completion date
31/08/2023

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 22/10/2024:
1. 18 to 65 years old
2. Sign the informed consent form
3. Outpatient with sore throat with the 7 clinical signs: Throat pain in the oropharynx
Fever, Oropharyngeal redness, Oropharyngeal exudate, Tonsil hypertrophy, Lymphoid formation on the posterior pharyngeal wall, Cervical lymphadenopathy

Previous participant inclusion criteria:
1. 18 to 50 years old
2. Sign the informed consent form
3. Outpatient with sore throat with the 7 clinical signs: Throat pain in the oropharynx
Fever, Oropharyngeal redness, Oropharyngeal exudate, Tonsil hypertrophy, Lymphoid formation on the posterior pharyngeal wall, Cervical lymphadenopathy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
30

Key exclusion criteria
1. Having ongoing conventional treatment for angina
2. Having a known allergy to one of the constituents of the investigational product
3. Pregnant women
4. People with respiratory problems

Date of first enrolment
06/02/2023

Date of final enrolment
31/03/2023

Locations

Countries of recruitment
Benin

Study participating centre
Hospital and University Center of SURU-LERE area of Cotonou
RUE 1305 Cotonou. 1er arrondissement

Cotonou
Benin
06BP 2664

Sponsor information

Organisation
Ufr Pharmacie/ Faculte des Sciences de la Sante de Cotonou

Funder(s)

Funder type
University/education

Funder Name
Pharmacy Training and Research Unit of the Faculty of Health Sciences of the University of Abomey-Calavi

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request
hganfon@yahoo.fr

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other unpublished results			22/10/2024	No	No
Protocol file			20/02/2023	No	No