

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 11/03/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 22/10/2024	Condition category Signs and Symptoms	<input type="checkbox"/> 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

Prof Habib GANFON

ORCID ID

<http://orcid.org/0000-0002-1815-154X>

Contact details

01 Bp 188 Cotonou Campus du Champ de Foire

Cotonou

Benin

494 BP

+229 66196995

hganfon@yahoo.fr

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Non randomised study

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

Sore throat

Interventions

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

Intervention Type

Supplement

Primary outcome measure

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

Secondary outcome measures

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

Overall study start date

01/05/2022

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

30

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

Sponsor details

01 Bp 188 Cotonou Campus du Champ de Foire

Cotonou

Benin

494

+229 66196995

fss_cotonou@yahoo.fr

Sponsor type

University/education

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

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

01/04/2024

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?
Protocol file			20/02/2023	No	No
Other unpublished results			22/10/2024	No	No