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Clinical toxicology of Melagrião® syrup in healthy volunteers

Submission date
19/10/2017

Recruitment status
No longer recruiting

Registration date
13/03/2018

Overall study status
Completed

Last Edited
09/03/2018

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Melagrião® is a medicine made from six medicinal plants with known action in the respiratory tract (breathing system): Mikania glomerata, Cephaelis ipecacuanha, Aconitum napellus, Polygala senega, Myroxylon balsamum and Nasturtium officinale. The aim of this study is to evaluate the safety and the genotoxic (DNA-damaging) potential of Melagrião® syrup in healthy volunteers.

Who can participate?
Healthy volunteers aged 18-50

What does the study involve?
Participants are randomly allocated to take either Melagrião® syrup or a placebo (dummy medicine) as four daily doses for 28 uninterrupted days. Blood samples are taken and clinical and laboratory tests are performed at the start of the study, during the treatment period and at the end of the study.

What are the possible benefits and risks of participating?
If it is found to be safe this medication will be of great value for the treatment of respiratory (lung) diseases. Melagrião® can cause some gastric (stomach) disorders, vomiting and diarrhoea. Blood sampling is a safe procedure and may cause mild discomfort as well as a small purple spot that often resolves without major problems.

Where is the study run from?
Federal University of Ceara (Brazil)

When is the study starting and how long is it expected to run for?
May 2007 to October 2007

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Sérgio Pereira
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Protocol 255/07

Study information

Scientific Title
Clinical toxicology of Melagrião® syrup in healthy volunteers: a randomized parallel trial

Study objectives
Melagrião® syrup is safe to use in healthy volunteers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee of the Federal University of Ceará, accredited by the National Health Council / MS (Protocol 255/07), 11/08/2007

Study design
Double-blind single-centre placebo-controlled randomized parallel trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Respiratory diseases

Interventions
48 adult subjects were randomly divided into two groups: Placebo (n=24) and Melagrião® (n=24). In order to have a uniformity of the groups the volunteers were randomized by means of lottery, using sealed envelopes. The subjects were treated for 28 uninterrupted days with 120 mL of Melagrião® or Placebo, divided into four daily doses. Clinical and laboratory evaluations were performed in the pre-study, during the treatment period and after the end of the study. The genotoxicity of Melagrião® was investigated through the comet assay.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
Melagrião®

Primary outcome measure
1. The genotoxicity of Melagrião® investigated through the comet assay at baseline and after 28 days
2. Hematological, renal and metabolic functions, evaluated using hematological and biochemical examinations performed before, during (7th, 14th, 21st and 28th days) and after treatment

Secondary outcome measures
Adverse effects assessed by questionnaire every 7 days over the 28 days

Overall study start date
05/05/2007

Completion date
30/10/2007

Eligibility

Key inclusion criteria
1. Men and women aged 18-50 years
2. Body mass index (BMI) greater than or equal to 19 and less than or equal to 30
3. Good health conditions or without significant diseases, to medical judgment, according to the rules defined in the Protocol, and evaluations to which it was submitted: clinical history, pressure and pulse measurements, physical examination, ECG and complementary laboratory tests

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
Both

Target number of participants
48

Key exclusion criteria
Positive response to any of the following criteria excluded the study volunteer:
1. Hypersensitivity to components of the formulation under study or history of serious adverse reactions
history or presence of liver or gastrointestinal diseases or another condition that interferes with the absorption, distribution, excretion or metabolism of the drug
2. Use of maintenance therapy with any drug except oral contraceptive; history of liver, kidney, lung, gastrointestinal, epileptic, haematological or psychiatric disease
3. Hypo or hypertension of any etiology that needs pharmacological treatment
4. Have a history or had myocardial infarction, angina and/or heart failure
5. Smokers (more than 10 cigarettes per day)
6. Ingestion of more than 5 cups of coffee or tea per day
7. Use of alcohol or illicit drugs; use of regular medication within 4 weeks prior to initiation of treatment of this study
8. Use of any medication within one week before starting treatment of this study
9. Hospitalization for any reason during the eight weeks prior to the start of treatment of this study
10. Pregnant or breastfeeding
11. Treatment within three months prior to the study with any drug known to have a well-defined toxic potential in large organs
12. Participation in any experimental study
13. Ingestion of any experimental drug within the three months preceding the start of this study

14. Donation or loss of 450 mL or more of blood within three months prior to initiation of treatment of this study or donation of more than 1500 mL within 12 months prior to initiation of treatment in this study

Date of first enrolment
12/08/2007

Date of final enrolment
30/08/2007

Locations

Countries of recruitment
Brazil

Study participating centre
Federal University of Ceara
60020-181

Sponsor information

Organisation
Federal University of Ceará

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Sponsor type
University/education

ROR
https://ror.org/03srtnf24

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Publication in a high-impact peer reviewed journal.

Intention to publish date
30/07/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Sérgio Luís da Silva Pereira (luiss@unifor.br).

IPD sharing plan summary
Available on request