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A randomised, placebo-controlled study of the effect of three herbal extracts (Condothymus capitatis, Origanum dictamnus and Salvia fruticosa/promifera) on the inflammatory reaction during infection of the upper respiratory tract

Submission date 06/06/2014	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 27/06/2014	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 09/07/2014	**Condition category** Respiratory	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol

Background and study aims

Infections of the upper respiratory tract are a common and frequent health problem with a significant economic impact, mainly due to loss of productivity but also due to increasing costs of prevention and treatment. Vaccines for seasonal influenza provide the basic cover but not all are vaccinated against these viruses. Hence there is a continuous need for treatment, prevention and relief from symptoms of influenza and other viruses affecting the upper respiratory tract. The study will look into the antiviral effect of an extract of three aromatic herbs of Crete/Greece in a pre-selected group of healthy volunteers who will have symptoms of seasonal flu. Previous research have shown both the antioxidant and antiviral/antibacterial properties of aromatic herbs, but so far no study has attempted to evaluate the effectiveness of the extracts of these herbs. Hence, the main aim is to find out the effectiveness of three herbal extracts compared with a placebo (dummy) tablet.

Who can participate?

Healthy adults will be selected and enrolled in the study. Participants will have to be able to visit one of the study centers within 24 hours from the start of common cold symptoms.

What does the study involve?

Participants will be randomly allocated to receive either the study product or placebo. Patients who receive the study product will undergo the corresponding tests scheduled for the first treatment visit and will complete the questionnaire to find out the intensity/severity of the symptoms, and will provide a blood sample as well as sample from the throat mucus via a throat swab for further tests and virus identification. The participant will receive the study product or placebo for 7 days, and will come back to the study center after this period for the final

treatment visit. In addition, participants will receive a telephone call every day in order to record their state of health and the duration and severity of their symptoms.

What are the possible benefits and risks of participating?
Although it may not directly benefit all patients participating in the study, it will provide important information that will help doctors in offering better treatment for common cold symptoms. The risks associated with participation in the study are minimal. Apart from the blood sample and throat swab sample there are no other invasive methods involved. There will be no personal compensation for participation in the study.

Where is the study run from?
The patients participating in the study will have to visit one of the following study centers in Greece:
1. Primary Health Care Unit of the Social and Family Medicine Clinic of the University Hospital of Heraklion
2. Charakas Health Care Centre
3. Ano Viannos Health Care Centre

When is the study starting and how long is it expected to run for?
The study started in November 2013 and finished in February 2014.

Who is funding the study?
The study is sponsored by Olvos Science A.E., Greece.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2011-OLV-HERB-01

Study information

Scientific Title
A randomised, placebo-controlled study of the effect of three herbal extracts (Condothymus capitatis, Origanum dictamnus and Salvia fruticosa/promifera) on the inflammatory reaction during infection of the upper respiratory tract: an interventional, randomised, double-blind, parallel groups comparative study

Study objectives
Please note that this trial has been amended
1. The anticipated start date of this trial was changed to 10/10/2013; previously this was 01/01/2014
2. The anticipated end date of this trial was changed to 10/02/2014; previously this was 01/04/2014
3. The number of participants has been reduced to 100 in total; the previous number of participants was 110
An amendment has also been made to the secondary outcome measures (see section)

To evaluate the administration of three herbal extracts versus placebo on the inflammatory response during infection of the upper respiratory tract (Upper Respiratory Tract Infection, URTI) with the aid of the Wisconsin Upper Respiratory Symptom Survey 21 questionnaire (WURSS-21).

Ethics approval required
Old ethics approval format

Ethics approval(s)
7th Health Prefecture or Crete - General University Hospital of Heraklion, 05/09/2012, ref. 9186

Study design
Interventional randomised double-blind parallel groups comparative study

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Infections and Infestations, Upper Respiratory Tract Infections

Interventions
1. Test product: dosage: 1 ml extract from Coridothymus capitatus + Origanum dictamnus + Salvia fruticosa/promifera dissolved in olive oil prepared in soft gel capsules.
Mode of administration: Oral
Duration of administration: 7 days

2. Placebo: dosage: olive oil, 1 ml/ in soft gel capsule
Mode of administration: Oral
Duration of administration: 7 days

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Recording of the severity of symptoms of upper respiratory infection in the test and in the control group with the aid of the WURSS-21 questionnaire
2. The average duration of the symptoms of URTI in the test and control groups

Secondary outcome measures
Current secondary outcome measures as of 09/07/2014
Mean change in C-reactive protein (CRP) levels from the start of administration and day 7, between the test and the control group

Previous secondary outcome measures
1. Mean change in C-reactive protein (CRP) levels from the start of administration and day 7, between the test and the control group
2. Mean change in viral load from the start of administration and day 7 between the test and the control group

Safety: the percentage of the participants that experienced an adverse event (AE) during the treatment administration period of the investigational product (7 days) will be recorded. Incidence, relatedness, severity, intensity and action taken regarding the investigational product will also be recorded.

Overall study start date
10/10/2013

Completion date
01/04/2014

Eligibility

Key inclusion criteria
1. Adults >18 years
2. Signed and dated informed consent form
3. Capability and availability to visit one of the study centers within 24 hours of onset of URTI symptoms (common cold)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Pregnancy or lactation
2. Antibiotics use (any type and route of administration) up to 14 days prior to inclusion in the study
3. Use of antiretroviral pharmaceutical medications or herbs from Crete
4. Participation in interventional clinical study during the period of the study conduct
5. Requirement for long-term administration of aspirin, non-steroid anti-inflammatory agents or other antipyretic/analgesic medicines (such as paracetamol). Use of low dosage aspirin for the prevention of cardiovascular events is excluded
6. Use of immunosuppressive medication including the systemic administration of steroids or other cancer therapy, and/or the presence of neoplastic disease or AIDS
7. Planned surgery or other invasive procedure requiring systemic anesthesia during the period of the study conduct

Date of first enrolment
10/10/2013

Date of final enrolment
01/04/2014

Locations

Countries of recruitment
Greece

Study participating centre
University of Crete
Herakleion

Greece
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Sponsor information

Organisation
Olvos Science SA (Greece)

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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
Olvos Science SA (Greece), ref 2011-OLVOS-HERB-01

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration