

The roles of essential oils in the modulation of immune function: a pilot study

Submission date
20/06/2005

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
21/09/2005

Overall study status
Completed

☐ Statistical analysis plan

☐ Results

Last Edited
13/09/2011

Condition category
Haematological Disorders

☐ Individual participant data

☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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2480

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

ECN-04-52

Study information

Scientific Title

Study objectives

That aromatherapy essential oils applied topically over a 28 day period are potentially effective in modulating immune alterations, including those associated with smoking; and that they can form a safe and well-tolerated treatment.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet**Health condition(s) or problem(s) studied**

Immunomodulation in smokers/non-smokers

Interventions

A blend of essential oils, at a total of 10%, in a carrier of unfragranced white lotion base.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

A blend of essential oils

Primary outcome measure

Alterations in the immune system indicators being measured will be estimated via a series of blood tests; the measures include in vivo changes in:

1. Complete blood count including leucocyte count and differential
2. Lymphocyte subset phenotype

3. Natural killer cell activity
4. Erythrocyte sedimentation rate (ESR)
5. C-Reactive protein: high sensitivity assay (hsCRP)

Secondary outcome measures

Secondary outcome measures include in vivo alterations in:

1. Lymphocyte cytokine production profile
2. Liver function tests
3. Urea, creatinine and electrolytes

Overall study start date

01/06/2005

Completion date

30/09/2005

Eligibility

Key inclusion criteria

Participants are to be:

1. Aged 18-60 years
2. Male
3. Willing to comply with study protocols
4. The smokers must consume 10 cigarettes per day, and have done so for at least a year
5. The non-smokers must have never smoked

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

60 Years

Sex

Male

Target number of participants

20

Key exclusion criteria

Factors resulting in exclusion include:

1. any significant medical problem or chronic illness including the findings on assessment of:
 - a. Body mass index (BMI) >30 or <18
 - b. Undiagnosed hypertension
 - c. Pulse irregularities consistent with pathological cardiac dysrhythmia such as atrial fibrillation

2. History of allergies to fragrances
3. Current or recent dermatitis
4. Regular use of medications
5. Vitamin or supplement consumption
6. Alcohol intake of more than 7 standard drinks per week or greater than 4 on heaviest day
7. High levels of exercise (extreme strenuous exercise for over 60 min >twice per week)
8. Recreational drug use
9. Any acute illness or infection in the preceding 2 weeks

Date of first enrolment

01/06/2005

Date of final enrolment

30/09/2005

Locations

Countries of recruitment

Australia

Study participating centre

P.O. Box 157

Lismore

Australia

2480

Sponsor information

Organisation

Fragrantia Investments (Australia)

Sponsor details

38 Dudley Road

Wonga Park Victoria

Australia

3155

Sponsor type

Industry

Funder(s)

Funder type

Industry

Funder Name

Sharon Kepper Aromatherapy - FrAGRANTIA Investments (Australia)

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