

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

<b>Submission date</b> 20/06/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 21/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 13/09/2011	<b>Condition category</b> Haematological Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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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Australia  
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 - Frangrantia 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