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

Submission date	Recruitment status	Prospectively registered
20/06/2005	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
21/09/2005	Completed	Results
Last Edited	Condition category	Individual participant data
13/09/2011	Haematological Disorders	<ul><li>Record updated in last year</li></ul>

## Plain English summary of protocol

Not provided at time of registration

# Contact information

#### Type(s)

Scientific

#### Contact name

Dr Joan O'Connor

#### Contact details

P.O. Box 157 Lismore Australia 2480

# Additional identifiers

Protocol serial number

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

#### Study type(s)

Treatment

#### 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(s)

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)

# Key secondary outcome(s))

Secondary outcome measures include in vivo alterations in:

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

# 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** 

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Upper age limit

60 years

#### Sex

Male

#### 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

Study participating centre P.O. Box 157 Lismore Australia 2480

# Sponsor information

## Organisation

Fragrantia Investments (Australia)

# Funder(s)

## Funder type

Industry

#### Funder Name

Sharon Kepper Aromatherapy - Fragrantia Investments (Australia)

# **Results and Publications**

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration