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# Efficacy of matico (Buddleja globosa H.) on healing wounds and ulcers

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 18/10/2013 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 26/03/2014 | Completed | [_] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 26/03/2014 | Skin and Connective Tissue Diseases | [_] Record updated in last year |

**Plain English summary of protocol**
Background and study aims
Wounds and ulcers are a major issue for health care systems and for individuals.
The convention treatment (CT) is applying a tulle dressing over wound/ulcers on a weekly basis. As a result 80% of type-1 or type-2 wound/ulcers heal in six weeks.
Matico (Buddleja globosa H.) is a shrub from Chile recognized by the Chilean Government Health Care System as a medicinal plant that can help heal wounds and ulcers. There has been no previous studies to demonstrate its therapeutic efficacy and safety for external and internal lesions. If matico is a medicinal plant with healing properties, we expect a 30% improvement in the healing process, a significant reduction in cost, and the same or less adverse reaction compared to CT alone and an improved quality of life. The aim of this study is to assess how well an extract of matico works on type-1 or type-2 wound/ulcers.

Who can participate?
Men and women aged between 18 and 75, with type-1 or -2 wounds/ulcers, and body mass index between 20 and 35.

What does the study involve?
Participants are randomly allocated to receive conventional treatment (CT) or CT + matico cream.

What are the possible benefits and risks of participating?
The healing process is faster and cheaper.

Where is the study run from?
Primary Care Centre, Santiago, Chile

When is the study starting and how long is it expected to run for?
The study is expected to start in August 2013 and to recruit participants for one year.

Who is funding the study?
This study is fully funding by the National Commission for Scientific and Technological Research (CONICYT) through its National Fund for Research and Development in Health (FONIS) program (Chile).

Who is the main contact?
Prof. Sandro Bustamante

# Contact information

### Type(s)
Scientific

### Contact name
Prof Sandro Bustamante

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# Additional identifiers

### Protocol serial number
SA12I2322

# Study information

### Scientific Title
Efficacy of matico (Buddleja globosa H.) on healing wounds and ulcers: a randomized, comparative, open-label study

### Acronym
BUDDLEJA

### Study objectives
Conventional treatment plus topical matico (Buddleja globosa H.) is more effective to heal type 1 or 2 wounds and ulcers than conventional treatment alone.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
1. Ethics Committee of Investigation on Human Beings, University of Chile - School of Medicine, 09/04/2012
2. Ethics Committee Family Health Centre EEF, 28/08/2013

### Primary study design
Interventional

## Study design
Randomized comparative open-label study

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Wounds and ulcers healing

## Interventions
Visit 1 (week 1):
1. Inclusion/exclusion criteria flowchart, informed consent.
2. Baseline medical history, current medical status, physical examination. Participant randomly allocated to receive conventional treatment (CT) or CT + matico cream.
3. Wound/ulcer evaluation and data recording. Healing protocol according to study branch.

Visits 26 (weeks 26): Current medical status, physical examination, wound/ulcer evaluation and data recording. Healing protocol according to study branch.

## Intervention Type
Other

## Phase
Not Applicable

## Primary outcome(s)
1. Efficacy to heal type 1 or 2 wounds and ulcers
2. Time to heal type 1 or 2 wounds and ulcers
3. Security and adverse reactions
4. Medication compliance
5. Treatment cost for health system/patient

Timepoints for all primary outcomes will be measured at baseline, and weekly from week 1 to 6.

## Key secondary outcome(s)
1. Efficacy - ten parameters wil be used to evaluate healing efficacy; each parameter will be scored from 1 to 4 points, as is shown below:
1.1. Wound/ulcer visual aspect:
1.1.1. Eritematosus, one point
1.1.2. Redish, two points
1.1.3. Yellowish/pale, three points
1.1.4. Necrotic, four points
1.2. Wound/ulcer longer diameter (measured with a standard sterile plastic flexible ruler):
1.2.1. 0.0 to 1.0 cm, one point
1.2.2. 1.1 to 3.0 cm, two points
1.2.3. 3.1 to 6.0 cm, three points
1.2.4 6.1 cm or bigger, four points
1.3. Wound/ulcer depth (measured with a standard sterile plastic flexible ruler):
1.3.1. 0.0 cm, one point
1.3.2. 0.1 to 1.0 cm, two points
1.3.3. 1.1 to 3.0 cm, three points

1.3.4. 3.1 cm or bigger, four points
1.4. Wound/ulcer exudate quantity:
1.4.1. No, one point
1.4.2. Scarce, two points
1.4.3. Mild, three points
1.4.4. Plentiful, four points
1.5. Wound/ulcer exudate quality:
1.5.1. No, one point
1.5.2. Opaque, two points
1.5.3 Turbid, three points
1.5.4. Purulent, four points
1.6. Wound/ulcer necrotic tissue:
1.6.1. No, one point
1.6.2. Less than 25%, two points
1.6.3. 25% to 50%, three points
1.6.4. More than 50%, four points
1.7. Wound/ulcer granulatory tissue:
1.7.1. 100% to 75%, one point
1.7.2. 75% to 50%, two points
1.7.3. 50% to 25%, three points
1.7.4. 25% or less, four points
1.8. Wound/ulcer oedema:
1.8.1. No, one point
1.8.2. +, two points
1.8.3. ++, three points
1.8.4. +++, four points
1.9. Wound/ulcer pain:
1.9.1. 0 to 1, one point
1.9.2. 2 to 3, two points
1.9.3. 4 to 6, three points
1.9.4. 7 to 10, four points
1.10. Wound/ulcer surrounding skin parameters:
1.10.1. Normal, one point
1.10.2. Desquamated, two points
1.10.3. Eritematosus, three points
1.10.4. Macerated, four points

Total score qualify type of wound/ulcer:
10  15 points, type-1
16  21 points, type-2
22  27 points, type-3
28  40 points, type-4

2. Time to heal:
2.1. Number of days to get healthy tissue

3. Security and adverse reaction:
3.1. Qualitative description
3.2. Quantitative description

4. Medication compliance:
It is considered compliant if he/she attends at least five out of six programmed visits of healing process

5. Treatment cost:
5.1. Supplies expenses for health care system
5.2. Supplies and other expenses for participant

Timepoints for all secondary outcomes will be measured at baseline, and weekly from week 1 to 6.

### Completion date
30/06/2014

## Eligibility

### Key inclusion criteria
1. Men and women aged 18 to 75 years old
2. Type 1 or 2 wounds and ulcers
3. Body mass index between 20 and 35

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

### Sex
All

### Key exclusion criteria
1. Either allergy to matico shrub (Buddleja globosa H.) or to any constituents of matico extract phytomedicine
2. Diagnostic of allergic/irritative dermatitis
3. Any vascular disease or varicose ulcer (including diabetic foot)
4. Skin neoplasia
5. Wounds/ulcers caused by radiation, or cytostatic/steroid drugs

### Date of first enrolment
01/08/2013

### Date of final enrolment
30/06/2014

# Locations

**Countries of recruitment**
Chile

**Study participating centre**
**Phytopharmacology Lab**
Santiago
Chile
8380453

# Sponsor information

**Organisation**
National Commission for Scientific and Technological Research (CONICYT) (Chile)

**ROR**
https://ror.org/02ap3w078

# Funder(s)

**Funder type**
Government

**Funder Name**
National Commission for Scientific and Technological Research (CONICYT) (Chile)  National Fund for Research and Development in Health (FONIS)

# Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration