ISRCTN38989659 https://doi.org/10.1186/ISRCTN38989659

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomized comparative open-label study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

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
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 measure
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.

Secondary outcome measures

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.

Overall study start date
01/08/2013

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
182

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
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Sponsor information

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

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Sponsor type
Government

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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

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