

Echinacea purpurea in the prevention of acute upper respiratory tract infections in children

Submission date 01/12/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 21/01/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 21/01/2011	Condition category Respiratory	<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
Prof Sandro E Bustamante

Contact details
Phytopharmacology Lab
Molecular And Clinical Pharmacology Programme
ICBM
Faculty of Medicine
University of Chile
Santiago
Chile
Stgo-07
sbustama@med.uchile.cl

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Echinacea purpurea in the prevention of acute upper respiratory tract infections in children: a randomised, double-blind, placebo-controlled, multicentre trial

Acronym

EPIRA

Study objectives

Echinacea purpurea standardised extract prevents acute upper respiratory infections in children aged two to four years old.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Scientific Ethics Committee, South Metropolitan Health Service approved on the 13th April 2010 (ref: N°52/2010)

Study design

Multicentre double blind randomised placebo controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Acute respiratory infections (ARI)

Interventions

Patients will be randomised to receive Echinacea purpurea standardised extract or placebo for 6 weeks. The total duration of follow up will be 24 weeks. Patients and carers will follow the schedule below.

Visit 1a: Inclusion/exclusion criteria flow chart, informed consent.

Visit 1b (Baseline): medical history, current medical status, physical examination. Start first set of blind medication (5 ml/12 h, po).

Visit 2 (week 3): current medical status, physical examination. Start second set of blind medication (5 ml/12 h, po).

Visit 3 (week 6): current medical status, physical examination. End blind medication.

Visit 4 (week 10): current medical status, physical examination.

Visit 5 (week 14): current medical status, physical examination.

Visit 6 (week 19): current medical status, physical examination.

Visit 7 (week 24): current medical status, physical examination.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Efficacy to prevent ARI episodes
2. Security and adverse reactions
3. Medication compliance

Key secondary outcome(s)

1. Efficacy:
 - 1.1. Number of ARI episodes
 - 1.2. Duration of ARI episodes (days)
 - 1.3. Severity of ARI episodes (fever, cough, nasal secretions, difficult to breath)*
2. Security and adverse reaction:
 - 2.1. Qualitative description
 - 2.2. Quantitative description
3. Medication compliance:

It is considered compliant if he or she took at least 80% of the indicated dose by comparing the weight of bottles of study medication for patients prior to and after their intervention periods to determine the volume used.

*Criteria and scores available on request.

Completion date

11/12/2010

Eligibility**Key inclusion criteria**

1. Male/female healthy children aged 2 years to 4 years 11 months
2. Participants must be registered in just one of the seven centres of the study
3. A responsible adult must care him/her 24 hours/7 days of the child
4. Only one child per family may be enrolled
5. Parents must sign Informed Consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

2 years

Upper age limit

4 years

Sex

All

Key exclusion criteria

1. Children with any chronic pathology or immune system disease
2. Allergy to Asteraceae family (coneflowers, sunflowers)
3. Viral or bacterial disease, related or not to ARI, diarrhoea, vomiting or digestive symptoms at start date
4. Hepatic or renal insufficiency
5. Surgery or treatment with drugs that modify immunological system until 60 days previous to start date

Date of first enrolment

28/05/2010

Date of final enrolment

11/12/2010

Locations

Countries of recruitment

Chile

Study participating centre

Phytopharmacology Lab

Santiago

Chile

Stgo-07

Sponsor information

Organisation

Knop Laboratories (Chile)

ROR

<https://ror.org/043xarp69>

Funder(s)

Funder type

University/education

Funder Name

University of Chile (Chile) - Molecular And Clinical Pharmacology Programme and Primary Care And Family Health Department

Funder Name

Knop Laboratories (Chile)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration