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

Submission date	Recruitment status	[ ] Prospectively registered
01/12/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
21/01/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
21/01/2011	Respiratory	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Echinacea purpurea in the prevention of acute upper respiratory tract infections in children: a ramdomised, 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)

Primary study design
Interventional

Study design
Multicentre double blind randomised placebo controlled trial

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 hystory, 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. Eficacy:
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 Conset

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 cronic 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 insuficiency
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