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A study of the preventive effects of an Echinacea extract upon the occurrence of respiratory infections in healthy students

Submission date 18/10/2017	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 22/11/2018	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 23/04/2021	**Condition category** Respiratory	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Colds and flu are very common causes of illness that are usually fairly minor and which most often result from infections of the throat and chest. There is not much medical evidence for effective ways of preventing or combating colds and flu. The herbal remedy Echinacea contains substances have effects in “test-tube” scientific experiments that suggest it may strengthen immune responses in human beings. Although medical research evidence is limited, Echinacea has become a popular treatment with annual sales in the $100s of millions. The aim of this study is to find out if giving healthy students an Echinacea extract benefits them by reducing the numbers of colds and flu illnesses they suffer from and the total numbers of days on which they feel ill from these illnesses.

Who can participate?
Healthy male and female students aged 18-30

What does the study involve?
Participants are randomly allocated to take either three Echinacea-containing tablets or placebo (dummy) tablets per day over two periods of 3 weeks separated by a break of 1 week. The study lasts 7 weeks overall starting in late January-early February and finishing in late March-early April. The numbers of colds and flu illnesses they suffer from and the total numbers of days on which they feel ill from these illnesses are measured weekly by pre-arranged telephone calls.

What are the possible benefits and risks of participating?
Side-effects have not been reported from consuming Echinacea, although as a precaution those who have allergies to plants related to Echinacea such as sunflower seeds, are prone to food allergies, suffering any autoimmune disorders or are pregnant or breastfeeding are advised not to take part in the study.

Where is the study run from?
University of Wolverhampton (UK)

When is the study starting and how long is it expected to run for?
September 2000 to May 2001

Who is funding the study?
1. University of Wolverhampton (UK)
2. Quest Vitamins Ltd (UK)

Who is the main contact?
Dr David Maslin
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Res20A/Hp1

Study information

Scientific Title
A randomised, placebo-controlled pilot trial of the preventive effects of thermally stabilised Echinacea purpurea extract upon upper respiratory tract infections in healthy students (aged 18-30 years)

Study objectives
Extract of the herb Echinacea purpurea prevents symptoms of upper respiratory tract illness.

Ethics approval required

Old ethics approval format

Ethics approval(s)
University of Wolverhampton, School of Health Sciences Ethics Committee, October-November 2000

Study design
Single-centre prospective randomised double-blinded placebo-controlled parallel-group (30:30) clinical intervention trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Upper respiratory tract infections

Interventions
Randomised dose allocation of trial or placebo tablets of same size and shape with their identities concealed from supervisors, investigators and participants until outcome data collected and entered on a spreadsheet. The trial involves 3 academic supervisors, 5 Student Investigators (SIs) and 60 student subjects aged 18-30 years (12 per SI).

Intervention consists of daily oral intakes of either a trial dose of ca. 900 mg dried Echinacea purpurea as powder incorporated in 3 x 294 mg tablets or a control dose consisting of placebo tablets of the same size and shape as the trial dose.

Coin-tossing will be used to randomly allocate codes in pairs to either pre-filled Echinacea (heads) or placebo (tails) containers, and in their order of recruitment subjects will be allocated to these codes.
Dose to be taken with/without food either all together or spread through the day.

Dose period: Two consecutive 3-week periods separated by 1 week off-dose (i.e., treatment period 7 weeks in total).

Subjects: Students aged 18-30 recruited by personal contact of student investigators. Any person who is on prescribed medication needs to seek medical advice before taking Echinacea.

Numbers: This is a pilot study which has a target recruitment of 60 students in total.

Intervention Type
Supplement

Primary outcome measure
Incidence of illness and number of days of illness in each week - frequency of symptoms of infectious illness related to immunity (e.g., flu, cold, mouth ulcers) measured using appropriate scoring methods, and investigators monitor subjects' compliance and collect information regarding incidence/symptoms of infection weekly by pre-arranged telephone contact

Secondary outcome measures
1. Personal information of volunteer trial subjects (home living arrangements, sleeping habits, medications, supplement usage [including antioxidants], number of URTIs in preceding 12 months, stress, smoking, alcohol intake, exercise frequency), assessed using form completed by volunteer trial subject prior to start of dose-period (trial intervention)
2. Feelings of illness defined from list of URTI symptoms, recorded using weekly diary forms completed by SI for each of their 12 volunteer trial subjects by recording in daily tick-boxes (i.e., record of URTI incidence and days ill) weekly throughout the trial intervention
3. Missed doses, recorded using weekly diary forms completed by SI for each of their 12 volunteer trial subjects by recording in daily tick-boxes weekly throughout the trial intervention
4. Ill effects of the dose and where applicable symptoms, recorded using weekly diary forms completed by SI for each of their 12 volunteer trial subjects weekly throughout the trial intervention
5. Exercise frequency (minimum time-period per iteration 20 mins), recorded using weekly diary forms completed by SI for each of their 12 volunteer trial subjects by recording in daily tick-boxes weekly throughout the trial intervention
6. Doses taken, recorded using form with tick-boxes for each (dated) day of the trial completed by each of the 12 volunteer trial subjects daily throughout the trial intervention
7. Dietary intakes, recorded using diet diary of all the food and drink consumed completed by volunteer trial subjects over two 4-day periods in the 2nd and 7th weeks during the trial intervention
8. Subjective perceptions of subjects, recorded using follow-up questionnaire completed by each of the 12 volunteer trial subjects (including dose identity, benefit, side-effects) following the trial intervention

Overall study start date
04/09/2000

Completion date
31/05/2001

Eligibility

Key inclusion criteria
1. Age: 18-30 years
2. Male or female
3. Occupation: student
4. Health status: healthy

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
30 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Gastro-intestinal (i.e., gut) ailments at the time of the study
2. Previous anaphylactic shock
3. Proneness to food allergies (specifically including sunflower seeds)
4. Severe eczema
5. Autoimmune disorders such as lupus or rheumatoid arthritis
6. Pregnant or breastfeeding

Date of first enrolment
01/12/2000

Date of final enrolment
31/01/2001

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Wolverhampton
School of Health Sciences
Wolverhampton
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WV1 1LY

Sponsor information

Organisation
University of Wolverhampton

Sponsor details
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Sponsor type
University/education

Website
https://www.wlv.ac.uk/about-us/our-schools-and-institutes/faculty-of-science-and-engineering/school-of-sciences/#

ROR
https://ror.org/01k2y1055

Funder(s)

Funder type
University/education

Funder Name
University of Wolverhampton (funding of staff supervision, support and materials)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
Quest Vitamins Ltd (UK) (doses of Echinacea and placebo materials in tablet form)

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 23/04/2021:
The aim is to publish the results of this trial in BMC Complementary and Alternative Medicine. Planned submission is by 2018. The trial results will be sent to experts in the field of Echinacea research (Dr Bruce Barrett, Professor Rudolf Bauer).

Intention to publish date
01/11/2022

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

Previous publication and dissemination plan:
The aim is to publish the results of this trial in BMC Complementary and Alternative Medicine. Planned submission is by 2018. The trial results will be sent to experts in the field of Echinacea research (Dr Bruce Barrett, Professor Rudolf Bauer).

IPD sharing statement
The datasets generated during and/or analysed during the current study are/will be available upon request from
Dr Elizabeth O'Gara (E.OGara@wlv.ac.uk) and Dr David Maslin (david.maslin@wlv.ac.uk and david.maslin@yahoo.co.uk). Microsoft Excel data will be available from 01/12/2017 and will be shared by email with anyone for statistical analysis subject to approval by investigators named above. Permission for anonymised use was given as part of volunteer consent. Data records provided in the Excel database are anonymised. There are no known ethical or legal restrictions. There could potentially be some restrictions relating to the commercial company origin of the Echinacea and placebo materials tested in the trial. Any intention to publish commentaries relating to these materials should therefore be checked with the registrants.

IPD sharing plan summary
Other