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Preventive effects of Echinacea extract on cold and flu symptoms

Submission date
16/11/2018

Recruitment status
No longer recruiting

Registration date
22/11/2018

Overall study status
Completed

Last Edited
22/04/2021

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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 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 that 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.
This study aims to find out if giving generally healthy adults Echinacea herb powder 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?
Generally healthy adults

What does the study involve?
Participants will be randomly allocated to the intervention or control group. Individuals in the intervention group will be given Echinacea to take daily for 8 weeks, whereas individuals in the control group will be given a placebo to take daily for 8 weeks.

What are the possible benefits and risks of participating?
By recording a range of lifestyle factors, participants will recognise and thereby may seek to behave in a way that avoids adverse potential risk factors, and embrace healthy behaviors that reduce susceptibility to colds and flu.
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 breast-feeding are advised not to take part in the study.

Where is the study run from?
School of Health Sciences, University of Wolverhampton (UK)

When is the study starting and how long is it expected to run for?
September 2001 to May 2002

Who is funding the study?
Faculty of Science and Engineering, University of Wolverhampton (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
Protocol Ep/2

Study information

Scientific Title
Preventive effects of oral Echinacea purpurea dried herb extract against upper respiratory tract infections: a randomised double-blinded placebo-controlled trial

Study objectives
The extract of the herb Echinacea purpurea prevents symptoms of upper respiratory tract illness. Preventive effects are greatest amongst those with the worst recent history of upper respiratory tract illness.

Ethics approval required
Old ethics approval format

Ethics approval(s)

University of Wolverhampton, School of Health Sciences Ethics Committee, 23/11/2001, no reference number

Study design
Interventional prospective single-centre double-blinded parallel-group randomised placebo-controlled 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 digital format, please use the contact details to request a patient information sheet.

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

Interventions
Upper respiratory tract infection (URTI) scores will be taken during an 8 week pre-treatment period. After this, these secores are used to divide the subjects into lower and higher strata. From each of these strata (blocks of 4 individuals), 2 subjects will be randomised to receive Echinacea and 2 will be randomly allocated to receive the placebo using randomised number sequences generated by a statistician.
Participants allocated to receive Echinacea will take Echinacea orally daily, in the form of 88 mg dried pressed Echinacea purpurea juice as a powder together with powdered excipients and inert carrier materials amounting to a total of 500 mg in 1 cellulose capsule.
Participants allocated to the placebo group will receive 1 placebo cellulose capsule to take orally daily, containing physiological inactive filler materials of the same size, shape and colour as the trial dose.

Intervention Type
Supplement

Primary outcome measure
Upper respiratory tract infection incidence and severity, assessed at the baseline and weekly for the 8 week trial period using the severity scale of Grimm and Muller

Secondary outcome measures
1. The following baseline personal data, assessed by study investigators on a study-designed form following recruitment and prior to week 1 of the intervention dose period:
1.1. Gender
1.2. Age

1.3. BMI
2. The following lifestyle information, assessed using a self-report questionnaire at approximately week 4 of the intervention dose period:
2.1. Accomodation
2.2. Transport
2.3. Dietary supplements
2.4. Stress
2.5. Alcohol intake
2.6. Smoking
2.7. Exercise
3. Diet, assessed using a self-report diet diary form at week 4 of the intervention dose period
4. Subjective perceptions of benefit, side-effects and dose identification, assessed by questionnaire at week 8 of the intervention dose period

Overall study start date
04/09/2001

Completion date
31/05/2002

Eligibility

Key inclusion criteria
1. Aged 18-65
2. Generally healthy

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
120

Key exclusion criteria
1. Gastrointestinal 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
01/10/2001

Date of final enrolment
30/11/2001

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Wolverhampton
School of Health Sciences
Wolverhampton
United Kingdom
wv1 1ly

Sponsor information

Organisation
University of Wolverhampton

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Sponsor type
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ROR

https://ror.org/01k2y1055

Funder(s)

Funder type
University/education

Funder Name
University of Wolverhampton

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 22/04/2021:
We aim to publish the results of this trial in "Complementary Therapies in Clinical Practice". 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:
We aim to publish the results of this trial in "Complementary Therapies in Clinical Practice" Planned submission is by 2019. 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 David Maslin (david.maslin@wlv.ac.uk). Anonymised raw data will be provided in an Excel spreadsheet including baseline personal data (gender, age, BMI), data on

basic life styles and outcomes data. This will be available from 30/01/2020 for analyses replicating those in the planned publication. Participants gave consent prior to participation in the trial

IPD sharing plan summary

Other