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Randomised, double blind, placebo-controlled trial for testing the efficacy of a botanical formulation in reducing cold and flu symptoms

Submission date
08/09/2006

Registration date
25/09/2006

Last Edited
27/10/2009

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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

Study objectives
The immune-stimulating effects of this proprietary botanical blend (Resistex®) may aid in resisting community-acquired respiratory viruses.

Ethics approval required
Old ethics approval format

Ethics approval(s)
At the time of the trial, ethics approval was not common in China and the regulations were not clear as to under what circumstances it was required. Therefore the Principal Investigator assembled a group of independent professionals to critically review the study protocol and the ingredients of the botanical formula (based on Chinese herbs), which was tested. They acted as the equivalent of an Institutional Review Board and determined that the study intervention was unlikely to pose any safety risk to the participants. This review took place in early 1998.

Primary study design
Interventional

Study design
The study was a randomised, double-blind, placebo-controlled clinical trial that included 61 elderly participants.

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Common cold and flu

Interventions
The 61 participants were randomised to the control (placebo) group or to the low dose or high dose treatment group of Resistex®. All three groups took their dietary supplement capsules just once a day. The low dose group took two 450 mg capsules (900 mg total); the high dose group took three 450 mg capsules (1350 mg); and the control group took three placebo (wheat starch) capsules. All were instructed to take their capsules as directed every day for the first four weeks.

This segment was followed by a one week break during which no capsules were taken, and all subjects received a health check-up by a physician. After the break, the subjects took their capsules as directed over a series of two-weeks on/one week off periods for a total of 4.5 months. [Note: These breaks are a normal practice in TCM; they are incorporated to allow the immune system to take a periodic break from the up-regulating effects of the herbs.]

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Resistex®

Primary outcome(s)
The main outcome measures in this study were self-reports of the frequency, duration, and severity of cold and flu symptoms as compared with the pre-treatment assessment of the same variables. At the beginning of the study, all participants were queried about their cold and flu histories from the previous winter season (mid-November to end of March).

Cold and flu symptoms included: headache associated with fever; nasal discharge; sore throat; sneezing; and chills or fever. To help subjects determine the frequency of colds or flu, the following criteria were established:
1. Family physicians diagnosis of condition
2. Simultaneous experiencing of two or more symptoms within a week
3. Experiencing three or more symptoms without seeing a doctor.

The questions were:
1. How many times did you contract a cold or flu within the specified period?
2. When you had a cold or flu, how many days did it usually take before the symptoms were alleviated?
3. When you had a cold or flu, on a scale of one to five, how severe were the cold and flu symptoms? (1) barely noticeable, (2) mild, (3) moderate, (4) severe, (5) very severe

At the end of the study, the participants answered the same questions regarding the current winter season (mid-November to end of March).

Key secondary outcome(s)
The subjects were asked whether they experienced any adverse effects/reactions.

Completion date
31/03/1999

Eligibility

Key inclusion criteria
1. Aged 60 to 80 years old
2. Having a normal clinical chemistry profile (tested at baseline)
3. Physician clearance
4. Willingness to be randomised to the treatment or placebo groups and adhere to all aspects of the study protocol

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
1. Acute or serious chronic diseases
2. Currently taking prescription medication or non-steroidal anti-inflammatory drugs
3. Use of vitamin or mineral supplements within the past three months

4. A history of alcohol or drug abuse
5. Marked sleep disturbances, serious allergies or salient emotional or mood problems
6. A history of systemic infection, bone fracture or surgery

Date of first enrolment
01/04/1998

Date of final enrolment
31/03/1999

Locations

Countries of recruitment
China

Study participating centre
Chinese Center for Disease Control and Prevention
Beijing
China
100050

Sponsor information

Organisation
Radix Bioresearch Corporation (USA)

ROR
https://ror.org/024hp8310

Funder(s)

Funder type
Industry

Funder Name
Financial support from Radix Bioresearch Corporation (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration