

The efficacy of lifestyle changes based on the principles of yoga in the management of bronchial asthma

Submission date 08/10/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/10/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/08/2009	Condition category Respiratory	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Kishore Kumar Deepak

Contact details
Department of Physiology
All India Institute of Medical Sciences
Ansari Nagar
New Delhi
India
110029
+91 (0)11 2659 3370
kkdeepak@gmail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Effect of yoga on pulmonary function, mast cell activation and quality of life in bronchial asthma: a randomised controlled trial

Study objectives

There are several studies suggesting that yoga has a favourable effect on the frequency and severity of attacks, pulmonary functions, dependence on medication and quality of life in bronchial asthma. Nevertheless, very few of the previous studies are randomised controlled trials (RCT), and none of them have investigated any immunological mechanisms by which yoga might work in bronchial asthma.

Bronchial asthma is characterised by hyperreactivity of airways leading to airway obstruction, and is aggravated during stressful periods. Therefore yoga, which leads to improvement in respiratory function as well as stress reduction, is likely to be useful in the management of bronchial asthma.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Ethics Committee of All India Institute of Medical Sciences (AIIMS) for human studies approved the original protocol of the study on 9th February 2001 and amendments were approved on 7th January 2004.

Study design

Parallel-group randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Bronchial asthma

Interventions

Group I (yoga group) was given an integrated course on lifestyle based on the principles of yoga for 2 weeks while continuing with the conventional treatment. At the end of the 2-week training, participants were asked to continue the practice at home for an additional 6 weeks. Parameters were recorded at regular intervals (0 weeks, 2 weeks, 4 weeks and 8 weeks). During the follow-up period, the patients were expected to continue the yoga practice daily. Their compliance was monitored by a diary, which they brought at each visit.

Group II (control group) was a wait-listed control group. For the first 8 weeks, the patients in Group II did not receive any yogic intervention but they continued to receive conventional treatment. The parameters were recorded at regular intervals as in Group I. At the end of 8 weeks, the patients in Group II were also offered yoga intervention as for Group I, i.e. a two-week course.

Parameters from both the groups are recorded at regular intervals at 0 weeks, 2 weeks, 4 weeks and 8 weeks, although the last timepoint for recording parameters was not equally separated, taking our patients convenience and continued compliance into consideration, we have kept 4 week separation for last study visit.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Spirometric indices of pulmonary function
2. Eosinophilic cationic protein as a marker of the course of the disease
3. The degree of exercise-induced bronchoconstriction as percentage of fall in FEV1 with exercise challenge
4. Urinary concentration of the prostaglandin D2 metabolite, 11 beta-Prostaglandin F2a (11 beta-PGF2a), before and after the exercise challenge as a marker of mast cell activation

Recorded at regular intervals at 0 weeks, 2 weeks, 4 weeks and 8 weeks.

Secondary outcome measures

1. Asthma quality of life: quality of life was measured by using a self-administered Asthma Quality of Life Questionnaire (AQLQ) which is available in bilingual form, i.e. English and Hindi (local Indian language)
2. Frequency of rescue medication

Recorded at regular intervals at 0 weeks, 2 weeks, 4 weeks and 8 weeks.

Overall study start date

19/04/2002

Completion date

28/02/2006

Eligibility

Key inclusion criteria

The potential subjects (adults of either sex) went through a step-wise screening procedure which consisted of satisfying the following criteria:

1. Clinical history of episodic airway obstruction
2. Forced expiratory volume of one second (FEV1), or peak expiratory flow rate (PEFR) less than 80 percent of predicted normal and more than 10% or at least 200 mL increase in FEV1 15 minutes after administration of two puffs of salbutamol
3. Presence of at least two clinical criteria of mild or moderate bronchial asthma for at least 6 months

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

60

Key exclusion criteria

1. Any respiratory tract infection during the past 4 weeks
2. On systemic or oral corticosteroid therapy
3. Smokers (any one who had smoked during the last one year was considered a smoker)
4. Concomitant major illness such as coronary heart disease, renal disease or diabetes
5. Practiced yoga or any other similar discipline during 6 months preceding the study

Date of first enrolment

19/04/2002

Date of final enrolment

28/02/2006

Locations**Countries of recruitment**

India

Study participating centre

Department of Physiology

New Delhi

India

110029

Sponsor information

Organisation

Central Council for Research in Yoga & Naturopathy (CCRYN) (India)

Sponsor details

Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homeopathy

Ministry of Health and Family Welfare (Government of India)

Jawahar Lal Nehru Bhartiya Chikitsa Evam

Homeopathy Anusandhan Bhawan

61 - 65 Institutional Area, Janakpuri

Phankha Road

New Delhi

India

110058

+91 (0)11 2852 0430/0431/0432

ccryn@vsnl.net

Sponsor type

Research organisation

Website

<http://www.ccryn.org>

ROR

<https://ror.org/02h2r8882>

Funder(s)**Funder type**

Research organisation

Funder Name

Central Council for Research in Yoga & Naturopathy (CCRYN) (India)

Results and Publications**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan**

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results		25/05/2007		No	No
Results article	results	30/07/2009		Yes	No