

Relationship between birth weight, early growth patterns and cardiovascular disease risk on adult cardiac structure and function in Asian Indians

Submission date 01/06/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 05/06/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 31/07/2023	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

At any given age and body build, people from the India and surrounding areas get more heart disease and diabetes than Europeans. Research suggests that the risk of developing these disorders is related to growth during fetal life (while in the womb) and childhood. The reasons for this are unknown. Previous research has studied risk factors for heart disease and measures of arterial health (the heart and its arteries) in two cohorts of young Indian adults in New Delhi and Vellore. Their early growth was recorded in detail and it was found that risk factors (hypertension, pre-diabetes, blood fats) but not arterial health, were related to growth in early life. A relatively unresearched part of cardiovascular (heart) disease in South Asians is the health of the cardiac muscle itself. The aim of this study is to assess the structure and function of the heart muscle using echocardiography (a test that uses sound to create images of the heart) in 3,000 men and women from the same cohorts, and relate these to early life growth and to risk factors and lifestyle measurements in young adulthood in order to lead to future interventions to improve nutrition and growth in fetal life and childhood, and to encourage healthy adult lifestyles, that will prevent hypertension, diabetes and heart disease.

Who can participate?

All male and female subjects, aged over 40 years who have previously participated in the New Delhi and Vellore birth cohorts.

What does the study involve?

Participants are visited at home by field workers, who explain the study, provide information sheets, and obtain written informed consent. Information on lifestyle factors (tobacco and alcohol consumption, diet, physical activity, occupation and socio-economic status) and medical history (including cardiac events and procedures since the last follow-up) are updated. Participants are then invited to attend a clinic for an echocardiographic assessment of heart dimensions and function, measurement of wall thickness of the blood vessels in the neck using ultrasound, measurement of cardiometabolic risk factors (the risks of having diabetes, heart

disease or stroke) and an electrocardiogram (a test that uses sensors to check the hearts rhythm each time it beats). Participants have their body composition (percentage of fat, bone, water, and muscle) recorded using a scanner.

What are the possible benefits and risks of participating?

Participants may benefit from receiving an extensive assessment of their cardiac status (heart health). The blood tests may help to identify if they have diabetes or high cholesterol. This can help the treating physicians to advise them on management of their health status. If the study participant has been diagnosed previously have diabetes, hypertension or cardiac disease, the tests done in this research can give them an idea of their current status and therefore aid in appropriate management. There are no anticipated risks, as apart from experiencing discomfort during blood sampling and the low risk of low radiation exposure during the scans and ultrasounds.

Where is the study run from?

This study is being run from the University of Southampton and takes place in five clinics in India.

When is the study starting and how long is it expected to run for?

February 2015 to January 2022

Who is funding the study?

British Heart Foundation (UK)

Who is the main contact?

1. Professor Caroline Fall

chdf@mrc.soton.ac.uk

2. Dr Senthil Vasan

svk@mrc.soton.ac.uk

Contact information

Type(s)

Scientific

Contact name

Prof Caroline Fall

ORCID ID

<https://orcid.org/0000-0003-4402-5552>

Contact details

MRC Lifecourse Epidemiology Unit

University of Southampton

Southampton General Hospital

Southampton

United Kingdom

SO16 6YD

+44 23 80777624

chdf@mrc.soton.ac.uk

Type(s)

Public

Contact name

Dr Senthil Vasam

ORCID ID

<https://orcid.org/0000-0002-3630-6568>

Contact details

Oxford Centre for Diabetes, Endocrinology and Metabolism

Churchill Hospital

Oxford

United Kingdom

OX3 7LE

+44 75 75323737

Senthil.vasan@ocdem.ox.ac.uk

Additional identifiers**Protocol serial number**

18694

Study information**Scientific Title**

Childhood and young adult predictors of myocardial structure and function at age 45 years in the New Delhi and Vellore Birth Cohorts, India

Acronym

The IndEcho Study

Study objectives

1. The prevalence of myocardial abnormalities will be related to current cardiometabolic risk factors and those measured 12-16 years ago in young adulthood, and to smoking and lower physical activity.
2. Myocardial abnormalities will be associated with lower birth weight-for gestational age, lower weight in infancy, and faster BMI gain during late childhood. The associations with current cardiometabolic risk factors will be stronger in men and women who had lower birth or infant weight.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Southampton University, 11/04/2016, ref: RE:18694
2. Indian Council of Medical Research, - 01/04/2016, ref: No.50/7/TF-CVD/15-NCD-II
3. Christian Medical College, Vellore, 22/07/2015, ref: IRB No.9548 (OBSERVE)
4. Sundar Lal Jain Charitable Hospital, 13/08/2016, ref: SLJH/IEC/No.1
5. Health Ministry Screening Committee, New Delhi, India, 01/04/2016

Study design

Observational cohort study

Primary study design

Observational

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Cardiovascular disease, Type 2 diabetes, Obesity

Interventions

The current study is an observational study that involves two birth cohorts (New Delhi and Vellore Birth Cohort) in India. Both the cohorts were established during 1969-1972. About 18,000 babies born in the area were measured at birth (weight, height) and subsequently followed up during infancy, childhood, adolescence and early adulthood, with record of weight and height at each time point and additionally for cardiovascular risk factors in early adulthood. The current IndEcho protocol targets about 3700 participants (from both cohorts) who have reached about 40 years of age.

Participants are visited at home by field workers, who explain the study, provide information sheets, and obtain written informed consent. Information on lifestyle factors (tobacco and alcohol consumption, diet, physical activity, occupation and socio-economic status) and medical history (including cardiac events and procedures since the last follow-up) are updated.

All participants are then invited for a clinic visit where detailed medical examination, anthropometric measurements (height, weight, waist circumference, hip circumference, skin fold thickness), body composition assessment (using Bioimpedance and/or DXA), hand grip strength assessment and cardiovascular status assessment using electrocardiography (ECG), echocardiography and carotid intima medial thickness measurements is taken. Additionally blood tests for glucose and insulin following oral glucose tolerance test, lipids and urine for protein are measured. Medical history and history of dietary habits, physical activity, socio-economic status are collected using standardised validated questionnaires.

The study is expected to last 36 months. This includes the time from recruitment of the first study participant to completion of the last participant. There is no involvement of the participant after their clinic visit for any other purpose related to the study. The period may also include the data analysis and publication of primary results if the recruitment is completed before the anticipated 36 months.

Intervention Type

Behavioural

Primary outcome(s)

1. Left ventricular mass and indices of left ventricular systolic and diastolic function assessed by echocardiography at study visit
2. Carotid intima media thickness assessed using ultrasound at study visit
3. Ischemic changes in the heart as assessed by electrocardiogram (ECG) at study visit

Key secondary outcome(s)

1. Body composition as assessed by anthropometry, bioimpedance and dual energy X-ray absorptiometry (DXA) at study visit
2. Glucose intolerance and lipid disorders as assessed by biochemical tests at study visit
3. Socio-economic status as assessed by Standard of Living questionnaire at study visit
4. Dietary pattern as assessed by Food frequency questionnaire at study visit
5. Physical activity as assessed by Global Physical Activity Questionnaire (GPAQ) at study visit
6. Birth weight and early growth data (already collected during previous follow-ups and available in cohort database) at study visit

Completion date

30/01/2022

Eligibility

Key inclusion criteria

1. Males and females
2. Aged over 40 years
3. Previously participated in the New Delhi and Vellore Birth Cohorts

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

40 years

Sex

All

Total final enrolment

2371

Key exclusion criteria

Individuals with history or on active treatment for chronic kidney disease or cancer.

Date of first enrolment

01/11/2016

Date of final enrolment

30/01/2022

Locations

Countries of recruitment

India

Study participating centre
Sundar Lal Jain Charitable Hospital
Ashok Vihar Phase -III
New Delhi
India
110052

Study participating centre
Christian Medical College
Vellore
India
632001

Study participating centre
Sitaram Bhartia Institute for Science and Research
B-16
Qutab Institutional Area
New Delhi
India
110016

Study participating centre
All India Institute of Medical Sciences
Ansari Nagar East
New Delhi
India
110029

Study participating centre
Centre for Chronic Disease Control
4th Floor
Plot number 47
Sector 44
Gurgaon
India
122002

Sponsor information

Organisation

Southampton University

ROR

<https://ror.org/01ryk1543>

Funder(s)

Funder type

Charity

Funder Name

British Heart Foundation

Alternative Name(s)

The British Heart Foundation, the_bhf, BHF

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Professor Caroline Fall Email: chdf@mrc.soton.ac.uk

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		13/07/2023	31/07/2023	Yes	No
Protocol article	protocol	10/04/2018	01/03/2021	Yes	No