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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

Registration date
05/06/2017

Overall study status
Completed

Last Edited
31/07/2023

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 Southhampton 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

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Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 lLal 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

Secondary study design
Cohort study

Study setting(s)
Community

Study type(s)
Prevention

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

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 measure
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

Secondary outcome measures
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

Overall study start date
10/02/2015

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

Age group
Adult

Lower age limit
40 Years

Sex
Both

Target number of participants
Target total recruitment of participants: 3700

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

Sponsor details
MRC Lifecourse Epidemiology Unit
University of Southampton
Southampton General Hospital
Southampton
England
United Kingdom
SO16 6YD

Sponsor type
University/education

Website
www.soton.ac.uk

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation

Alternative Name(s)
the_bhf, The British Heart Foundation, BHF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Results will be disseminated through scientific meetings and peer-reviewed journals. The first publication intended is the study protocol in a peer-reviewed journal (2017). Following completion of data collection (expected end of 2018) and cleaning, analysis related to specific research questions will begin. The results are likely to be published from mid 2019.

Intention to publish date
30/08/2023

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?
Protocol article	protocol	10/04/2018	01/03/2021	Yes	No
Results article		13/07/2023	31/07/2023	Yes	No