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Relationship between maternal egg intake and foetal development

Submission date	Recruitment status	[ ] Prospectively registered
14/08/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
03/12/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
15/12/2008	Nutritional, Metabolic, Endocrine	[ ] 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
Daily consumption of whole eggs during pregnancy promotes foetal growth and development in children born to low-income women.

Ethics approval required

Old ethics approval format

Ethics approval(s)
1. Rutgers Human Subjects Investigational Review Board, approved on 20/05/2008
2. State University of Rio de Janeiro Human Subjects Ethics Board, approved in January 2008

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Maternal nutrition and foetal development

Interventions
The participants are allocated to four study arms:
Group 1: Normal dietary intake who never consume eggs (non-random allocation)
Group 2: Normal diet who are instructed not to consume eggs (random allocation)
Group 3: Normal diet who are instructed to eat at least one egg per day (random allocation). They will be provided with vouchers redeemable at local stores for the purchase of eggs only.
Group 4: Control group (non-random allocation). They will be provided with standard dietary counselling for pregnant women.

Total duration of interventions: Three months

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Eggs

Primary outcome(s)
1. Foetal growth, measured at 3 months and 6 months of gestation
2. Newborn ponderal index, measured at birth
3. APGAR score, measured at birth

Key secondary outcome(s)
1. Maternal body composition, measured at 3 months of gestation
2. Newborn body composition, measured at birth

Completion date
01/09/2010

Eligibility

Key inclusion criteria
1. Women between the ages of 18 and 40 years
2. Those who are in their 4th or 5th month of singleton pregnancy
3. Free from chronic diseases (heart disease, cancer, diabetes, hypertension, and other disorders that may influence metabolism and growth)
4. Reside in Duque de Caxias in Rio de Janeiro

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

Key exclusion criteria
1. Women who are beyond their 6th month of pregnancy
2. Pregnant with more than one foetus
3. Current use of tobacco, alcohol or illegal drugs
4. Younger than 18 or older than 40 years of age

Date of first enrolment
01/09/2008

Date of final enrolment
01/09/2010

Locations

Countries of recruitment
Brazil

United States of America

Study participating centre
Rutgers, The State University of New Jersey
New Brunswick
United States of America
08901

Sponsor information

Organisation
Egg Nutrition Center (USA)

ROR
https://ror.org/00289h314

Funder(s)

Funder type
Industry

Funder Name
Egg Nutrition Center (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration