

Relationship between maternal egg intake and foetal development

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| Submission date 14/08/2008 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 03/12/2008 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 15/12/2008 | Condition category Nutritional, Metabolic, Endocrine | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> 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

Protocol serial number
N/A

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

Study design

Randomised controlled trial

Primary study design

Interventional

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