

Infant anthropometry and body composition in Ethiopia

Submission date 08/12/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 10/01/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 11/03/2024	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
<http://www.ju.edu.et/jucan/>

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Predictors of neonatal and early infant body composition and growth and its effect on health in Jimma, Ethiopia: an observational study of infant body composition using infant air displacement plethysmography

Acronym

iABC

Study objectives

The rationale for the study is that little is known about fat and lean mass development in foetal and early life, in particular in the studies population. Answering the following questions will provide new understanding of body composition in early life:

1. What are the fat and lean mass levels at birth?
2. Which maternal and infant factors predict neonatal body composition?
3. Which maternal and infant factors - including birth weight - predict changes in fat and lean mass from 0 to 6 months?
4. What is the relationship between birth weight and 6 month body composition?
5. What is the relationship between neonatal body composition and infant morbidity and growth?

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Jimma University Ethical Review Committee approved on the 23rd December 2008 (ref: RPO /56/2001) (Air Displacement Plethysmography Study)
2. Jimma University Ethical Review Committee approved on the 12th October 2009 (ref: RPGC /J05/2002) (Deuterium Dilution substudy)

N.B. The reference numbers are based on the Ethiopian calendar, which is approximately 8 years behind the Gregorian calendar

Study design

Observational cohort study with nested cross-sectional study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

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

Health condition(s) or problem(s) studied

Neonatal and infant fat and lean mass

Interventions

Neonatal and infant body composition is measured using infant air displacement plethysmography (PeaPod, Life Measurement, Inc). On a subsample of 120 individuals infant body composition is measured using deuterium dilution. Maternal body composition is measured using bio-impedance analysis (BC-418MA, Tanita B.V.). Anthropometry are measured using conventional methods, and questionnaire information is taken orally in local language.

The duration of the study is 6 months, as newborns and mothers are assessed 6 times: at birth, 6, 10, 14, 18 and 26 weeks of age. Duration of follow-up is also 6 months.

Contact details for Ethiopian Principal Investigator:

Dr Tsinuel Girma
Department of Pediatrics and Child Health
PO Box 574
Jimma
Ethiopia

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Fat and lean mass at birth, 6-, 10-, 14-, 18- and 26 weeks of age, measured with infant air displacement plethymography and deuterium dilution (in a sub-sample)

Secondary outcome measures

Anthropometry and self-reported (by the mother) morbidity at birth, 6-, 10-, 14-, 18- and 26 weeks of age

Overall study start date

17/12/2008

Completion date

01/01/2012

Eligibility

Key inclusion criteria

1. Pregnant mother aged between 15 - 45 years
2. Currently living in Jimma town
3. Planning to stay in Jimma town for at least 6 months after birth
4. Consent is given
5. Children are between 0 - 6 months of age

Participant type(s)

Patient

Age group

Adult

Lower age limit

15 Years

Upper age limit

45 Years

Sex

Female

Target number of participants

350

Total final enrolment

378

Key exclusion criteria

1. Birth weight less than 1500 g
2. Congenital malformation

Date of first enrolment

17/12/2008

Date of final enrolment

01/01/2012

Locations**Countries of recruitment**

Denmark

Ethiopia

Study participating centre

University of Copenhagen
Frederiksberg C.
Denmark
1958

Sponsor information

Organisation

University of Copenhagen (Denmark)

Sponsor details

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DK-1017
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ku@ku.dk

Sponsor type

University/education

Website

<http://ku.dk>

ROR

<https://ror.org/035b05819>

Funder(s)

Funder type

Industry

Funder Name

Danida (Denmark)

Funder Name

University of Copenhagen (Denmark) - Faculty of Life Sciences

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?
Results article	results	01/10/2013		Yes	No
Results article	results	01/10/2019	21/06/2019	Yes	No
Results article	results	01/11/2019	12/09/2019	Yes	No
Results article	results	01/07/2018	17/09/2019	Yes	No
Results article		14/06/2023	19/06/2023	Yes	No
Results article		06/03/2024	11/03/2024	Yes	No