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Infant anthropometry and body composition in Ethiopia

Submission date	Recruitment status	[ ] Prospectively registered
08/12/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/01/2011	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/03/2024	Pregnancy and Childbirth	

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.
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1958

Sponsor information

Organisation
University of Copenhagen (Denmark)

Sponsor details
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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