# Infant anthropometry and body composition in Ethiopia

Submission date	Recruitment status  No longer recruiting	<ul><li>Prospectively registered</li></ul>		
08/12/2010		☐ 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

#### Contact name

Prof Henrik Friis

#### Contact details

University of Copenhagen Department of Human Nutrition Rolighedsvej 30 Frederiksberg C. Denmark 1958

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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

Nørregade 10 Copenhagen Denmark DK-1017 +45 35 32 26 26 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 Results article		14/06/2023 06/03/2024	19/06/2023 11/03/2024	Yes Yes	No No