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Effect of nutritional supplements on lean body mass, general health and disease progression of human immunodeficiency virus (HIV) positive lactating mothers and the ensuing effects on their infants including the impact of feeding mode on disease progression in the infected infants

Submission date
19/01/2011

Recruitment status
No longer recruiting

Registration date
07/02/2011

Overall study status
Completed

Last Edited
06/06/2012

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
Effect of nutritional supplements on lean body mass, general health and disease progression of human immunodeficiency virus (HIV) positive lactating mothers and the ensuing effects on their infants including the impact of feeding mode on disease progression in the infected infants: a prospective observational study with a nested randomised controlled trial

Study objectives
1. Breastfeeding will not negatively impact on mothers' lean body mass; nutritional status; disease progression and psychological indices
2. Exclusive breastfeeding versus formula feeding will reduce diarrhoeal morbidity; improve growth and developmental indices in the HIV exposed negative infants and would improve outcome in HIV infected infants
3. Nutritional supplementation provided to HIV infected lactating women will improve their lean body mass; nutritional status and health
4. Nutritional supplementation provided to HIV infected lactating women will improve the quality of breastmilk

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of KwaZulu-Natal, Durban, Ethics Committee approved on the 6th May 2006 (ref: H081 /05)

Study design
Prospective observational study with a nested randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Human immunodeficiency virus (HIV)

Interventions
The intervention used was a ready to use micronutrient enriched peanut/soy milk food paste available locally and being used by our national department of health as a supplement in HIV wasting and malnutrition. It was donated to us by the "Gift of the givers" foundation (website: http://www.giftofthegivers.org/). The supplement is called Sibusiso ready food supplement.

Daily dose of the supplement was 50g orally. The total duration the supplement was given was 6 months and the follow-up of all patients was 9 months.

The control arm received non-nutritive supplements like tea, soap, shampoo.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Clinical assessments including WHO disease staging and anthropometric measurements (weight, length/height, mid-upper arm circumference, triceps skinfold thickness and head circumference [infants]) were done at baseline and monthly till six months and last visit at nine months in both mother and child
2. CD4 counts and laboratory assessments at baseline and six months in the mother
3. Body composition measurements in mothers every at baseline and every three months till nine months using: saliva samples and deuterium enrichment method (FTIR - Fourier transform infra red spectroscopy) and BIA (Bioelectrical Impedance analysis)
4. The WHO Self reporting questionnaire (SRQ 20) and 24 hour dietary recall every three months in the mother
5. Infant feeding history at baseline and monthly till six months, then at nine months
6. HIV DNA PCR was done on the child at six weeks and nine months. If positive at six weeks, it was repeated at ten weeks. CD4 counts and safety bloods were done on all positive infants to assess for antiretroviral eligibility and to start treatment.

Key secondary outcome(s))
No secondary outcome measures

Completion date
15/04/2009

Eligibility

Key inclusion criteria
1. HIV positive pregnant women
2. Not yet eligible for antiretroviral therapy, i.e., World Health Organization (WHO) Stage 1 or 2; or CD4 greater than 200
3. Resident in Cato Manor area in Durban, KwaZulu-Natal

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Women who had advanced disease (CD4 less than 200 or WHO stage 3 and 4 disease) were not eligible for participation and were referred to the anti-retroviral (ARV) treatment programme on site
2. Women who did not intend to stay within a 30 km radius of the clinic and would not be able to attend follow up visits
3. Any mother who gave birth to a baby with any congenital abnormality or with any complication during birth requiring specialized management
4. Gestation less than 36 weeks

Date of first enrolment
20/11/2006

Date of final enrolment
15/04/2009

Locations

Countries of recruitment
South Africa

Study participating centre
Room 257, 2nd floor
Durban
South Africa
4013

Sponsor information

Organisation
University of KwaZulu-Natal (South Africa)

ROR
https://ror.org/04qzfn040

Funder(s)

Funder type
Industry

Funder Name

Hasso Plattner Ventures (Germany) - fund administered through the University of KwaZulu-Natal, for consumables

Funder Name
International Atomic Energy Agency (IAEA) (USA) - funded all equipment used in the study

Results and Publications

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	22/12/2011		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes