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Effectiveness of generic split adult tablets and paediatric fixed dose combination (FDC) of d4T /3TC/NVP in the treatment of HIV infected Malawian children

Submission date	Recruitment status	[ ] Prospectively registered
12/05/2010	No longer recruiting	[ ] Protocol
Registration date	Overall study status	[ ] Statistical analysis plan
20/05/2010	Completed	[ ] Results
Last Edited	Condition category	[ ] Individual participant data
17/03/2011	Infections and Infestations	[ ] 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
394

Study information

Scientific Title
Effectiveness of generic split adult tablets and paediatric fixed dose combination (FDC) of d4T /3TC/NVP in the treatment of HIV infected Malawian children: A part open-label randomised controlled trial and part cohort study

Acronym
TrioPed

Study objectives
We examine the effectiveness of standard paediatric 1st line ART regimens in Malawi in HIV infected children eligible for ART according to national guidelines.

The aim of the study is examine the effectiveness of Triomune baby in children <10kg and compare effectiveness of split adult FDC of d4T/3TC/NVP (recommended 1st line paediatric regimen) with Triomune baby for children 10kg and above.

Please note that as of 23/06/10 details of the extended ethics approval have been added to this record. More details can be found in the relevant field with the above update date.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. National Health Sciences Research Committee (NHSRC), Lilongwe, Malawi, approved on the 7th of April 2008 (Protocol no: 394; approval valid until 16/3/2010)
2. Baylor College of Medicine, Houston, USA, approved on the 15th of May 2009 (Protocol no: H-23674; approval valid until 4/5/2011)

Added 23/06/10:
3. National Health Sciences Research Committee (NHSRC), Lilongwe, Malawi extended their approval on the 17th of March 2010 (Protocol no: 394; approval valid until 16/03/11)

Added 17/03/2011:
Approvals extended:
1. Baylor College of Medicine approval valid from 18/02/2011 to 25/01/2012
2. National Health Sciences Research Committee (NHSRC) of Malawi valid from 15/03/2011 to 14 /3/2012

Study design
Children with body weight 10kg and above: Open label, randomized controlled trial
Children less than 10 kg body weight: Cohort study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Human Immunodeficiency Virus (HIV)

Interventions
Two different formulations of generic fixed dose combination of d4T/3TC/NVP tablets are compared in children 10kg and above: split adult tablets and a specific paediatric formulation (Triomune babyTM). Children less than 10kg bodyweight will be only started on Triomune baby.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
d4T/3TC/NVP (didehydrodeoxythymidine [d4T] / dideoxythiacytidine [3TC] / nevirapine [NVP]) - generic and Triomune®

Primary outcome(s)
Proportion of children with viral load of <400 copies/ml at 12 months follow-up

Key secondary outcome(s))
1. Monitoring patients' clinical response during routine visits
1.1. Change in body weight and height (z-scores)
1.2. Proportion of patients dying and lost to follow up
1.3. Time from enrolment to death and lost to follow up
1.4. Proportion of patients presenting with new symptoms and signs from enrolment
1.5. Proportion of patients requiring hospital admission
2. Monitoring patients' immunological response (CD4 count adjusted for age at entry, 3, 6, and 12 months)
2.1. Proportion of patients with immunological failure
2.2. Time until immunological failure occurs from enrolment
2.3. Change of Median CD4 percentage
3. Monitoring patients' virological response (HIV RNA at Entry, 3, 6, and 12 months)
3.1. Proportion of children with HIV RNA <400 copies/ml
3.2. Mean plasma viral load log10 change adjusted to baseline value
3.3. Proportion of patients with virological failure:
3.3.1. HIV RNA not suppressed to undetectable levels (<400 copies/ml) at 6 months or
3.3.2. Less then 10fold (1 log10) decrease from baseline viral load after 6 months of ART or
3.3.3. Repeated detection of HIV RNA in children who had <400 copies/ml
3.3.4. A reproducible increase in viral load of children who had an substantial virological response but still have low levels of detectable HIV RNA who then had an greater than 3fold (>0.5 log10) increase in copy number (children ≥ 2 years)
3.4. Time until virological failure occurs from enrolment
4. Monitoring Adverse Reactions
4.1. Signs and symptoms likely to be related to ART according to routine clinic checklist
4.2. Laboratory:
4.2.1. Complete Blood Count (CBC)
4.2.2. Aspartate Aminotransferase (AST)
4.2.3. Alanine Aminotransferase (ALT)
4.2.4. Lipase
4.2.5. Creatinine
4.3. Proportion of patients requiring modification of dosing regimen (e.g. prolonged lead in phase, intermittent stop)

4.4. Proportion of patients permanently stop/withdrawn from initial regimen and/or started on alternative 1st line regimen
5. Proportion of patients with >95% adherence by reported or observed pill count during clinic visits
6. Proportion of patients with >95% adherence with medication intake (ART) according to pill counts during unannounced home visits
7. Proportion of patients presenting in the clinic upon agreed appointment
8. Proportion of patients with detectable and undetectable NVP drug- plasma concentration in samples taken during pharmcokinetics (PK) study
9. Proportion of patients with NVP levels above the threshold at steady state
10. Proportion of patients having HIV drug resistance at baseline, 6 and 12 month, or when study treatment needs to be discontinued

Completion date
01/08/2011

Eligibility

Key inclusion criteria
1. Confirmed HIV infection (either HIV antibody test or, if <18 months, by HIV DNA test)
2. Caregiver and child, if applicable, counselled about HIV infection
3. Age <15 years
4. Body weight ≥3kg and <25kg
5. Informed consent given by caregiver and child if applicable
6. Eligible to start Anti-Retroviral Therapy (ART) according to Malawi National ART guidelines (3rd edition 2008)
7. Likely to comply with the study protocol (e.g. a main caregiver, responsible for administrating medication has been identified, caregiver and child have undergone an ART education session using the national paediatric ART education flipchart to understand the implications of ART, patient lives within the Lilongwe district)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Upper age limit
15 years

Sex
All

Key exclusion criteria

1. Previous exposure to ART except Prevention of Mother-To-Child Transmission (PMTCT)
2. Patient requires hospital admission according to assessment of study clinician
3. Obvious liver disease on clinical examination (e.g. jaundice)
4. Obvious renal disease on clinical examination (e.g. lid oedema, hypertension)

Date of first enrolment
01/05/2008

Date of final enrolment
01/08/2011

Locations

Countries of recruitment
Malawi

Study participating centre
Lighthouse at Kamuzu Central Hospital
Lilongwe
Malawi
PO Box 106

Sponsor information

Organisation
Ministry of Health (Malawi) - HIV department

ROR
https://ror.org/0357r2107

Funder(s)

Funder type
Government

Funder Name
Ministry of Health (Malawi) - HIV department

Funder Name

Clinton Foundation (USA) - Malawi Country Office

Funder Name
German Agency for Technical Cooperation (Deutsche Gesellschaft für Technische Zusammenarbeit [GTZ]) (Germany) - Malawi Country Office

Funder Name
Private donor

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes