HUMAN AFRICAN TRYPANOSOMIASIS: CONDUCTING QUALITY TRIALS IN RESOURCE-POOR SETTINGS

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OUTLINE

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INTRODUCTION
Experiences Dipumba, RDC

- Site HATSENTINEL (WHO/CDC)
  - Collection of epidemiological and treatment data since 2001
- THARSAT study (ITM Antwerp)
- NECT: Dipumba’s first clinical trial
  - Local team’s first experience in a clinical trial
  - Members experienced in diagnostic and treatment of HAT
  - Local team
    - 2 physicians
    - 3 lab technicians
    - 8 nurses
  - Capacity: 30 beds, 40 patient treated / month
IMPLEMENTATION STAGES

- **A) Site rehabilitation** to improve working conditions of the team and hospitalisation conditions of the patients.
  - Laboratory
  - Blood and CSF sampling and examination room
  - Patient wards
  - infirmary
- **B) Mode of transport for the investigator**
  - Motorcycles
  - Fuel
IMPLEMENTATION STAGES (continued)  
(with the support of DNDi and STI Basel)  

C) Equipment – improving diagnostic methods for HAT and other underlying pathologies  
  □ Laboratory  
    ■ Reflotron (biochemistry testing)  
    ■ Centrifuge  
    ■ Hemocue (Hemoglobin dosage)  
    ■ Paracheck (quick malaria test)  
  □ Infirmery  
    ■ Aspirator  
    ■ Rechargeable solar lamps  
    ■ Tension metre, Thermometre, Scales etc...  
    ■ Cell phone (to call the Investigator / on-duty nurse)
IMPLEMENTATION STAGES (continued)
(with the support of DNDi and STI Basel)

- D) Training and capacity strengthening
  - Training for the team
    - Refresher course on HAT (DFMO/eflornithine treatment)
    - NECT Protocol
    - Good Clinical Practice
  - Capacity strengthening for Investigators
    - Neurology (10 day training in Neuropsychiatry)
    - Diagnosis and treatments, AE et SAE (by Epicentre)
    - Computer softwares (word, excel, power point)
  - Capacity strengthening for lab technicians
    - By PNLTHA
Daily schedule of the Investigator

- Includes
  - Informed consent
  - Physical examination of patients
  - Randomisation
  - Treatment preparation
- Daily clinical evaluation of patients
  - Vital signs, AE and their management
  - SAEs, their management and reporting
- Completing case report forms (CRF) and other documents

Follow-up Preparation

- Patient history and details : personal address, address of relatives, telephone number, etc.
- Validation of patient’s description of their address (during patient hospitalization)
- Incentive offered to patients when completing follow up at 6-12-18 months (mosquito net)
- Excellent patient/Doctor Relationship
Quality Control

- By investigator
  - Respecting the trial protocol and its annexes
  - Collecting data (patient file - CRF)
  - Drug supply management
- By monitors (numerous visits of the STI team)
  - Verify source data and trial documents (CRF, inventories, consent forms etc.)
  - Validating lab equipment and quality control
- By auditor
  - Confirming data quality and integrity by an independent auditor
- By sponsor (DNDi)
  - visits of the DNDi Team, making resources available (supplies, finances and equipment)
Challenges

- Throughout inclusions
  - Numerous documents (some in English only)
  - Limited technical means (paraclinical)
  - Limited internet access
  - Poverty of patients and lack of education
  - Refusal of signing informed consent forms
  - Non-included patients frustrated (food)

- Challenge to get receipts for some expenses
Challenges (continued)

- During follow up
  - Repeated address changes or phone number of patients
  - Bad road conditions
  - Motorcycles not well-adapted for bad road conditions (numerous technical problems)
  - Streets without names or not known within community
  - Feeling of being harassed
- No archive system (15 years)

Poor road conditions make some sites inaccessible by motorcycle
Strengths

- The team’s determination working in the Trial (Local team, PNLTHA, Epicentre, STI, DNDi)
- Efficient logistical support
- Efficient communication with partners
- Excellent Patient / Doctor Relationship
RESULTS
60 patients included at Dipumba
• 55 “available” at 18 month follow-up (f-u)
• 52 controlled at 18 months (95%)

F-u at 6 months

F-u at 12 months

F-u at 18 months

CONCLUSION

- NECT is a success
  - Final results of the multicentre study will be published in the *Lancet* online 25 June
- Enriching experience for the local team
  - Its first clinical trial
- NECT FIELD in progress
  - 20 patients included
- To come: FEXINIDAZOLE or others?
Thank you!