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Feasibility of NECT administration in rural health structures

Results from implementation in a multicentre clinical trial in the DRC

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Agenda

• Introduction NECT
• Methods
  • Feasibility assessment
• Results
  • Treatment adherence
  • Implementation
  • Confidence in treatment
  • Capacity & logistics
• Conclusions & Recommendations
Introduction

Background

NECT treatment

- 10 days nifurtimox - 15mg/kg/d p.o. TID
- 7 days eflornithine - 400mg/kg/d i.v. BID

➢ Listed on WHO essential medicines list in 2009
Methods

Rationale

• Implementation will depend on feasibility in limiting conditions
  • Basis
    • RCT Phase II/III trial in RoC / DRC 2003 – 2008
  • Continuation
    • Field trial in DRC „NECT-FIELD“
      ➢ Case management following national guidelines (PNLTHA) for HAT

• Objectives NECT-FIELD
  • Gather additional data on safety
  • Gather additional data on effectiveness
  ➢ Assess feasibility
    • Compliance, duration of hospitalisation, logistics, storage, resources…
**Methods**

**Feasibility assessment**

**Treatment adherence (by CRF)**
- Timing - doses & treatment duration
- Dosing - number of doses, amount of drug
- Hospitalisation period - duration
- Reasons for non-adherence

**Feasibility (by observation / interviews)**
- Observation of procedures during treatment
- Questionnaire based interviews of health staff
- Questionnaire based interviews and observation of logisticians
  - Site, provincial coordination and national directorate level
Results
Treatment adherence of patients – CRF based

Timing
- Compliance of application – i.e. within 0.5hr between first & last dose
  - Nifurtimox (every 8 hrs) 90%
  - Eflornithine (every 12 hrs) 93%
  - No treatment interruptions

Dosing
- Number of doses – i.e. 30x nifurtimox, 14x eflornithine
  - 96% compliant
  - Total amount of drug ± 5%
    - Nifurtimox 98%; Eflornithine 99%
Results

Treatment adherence of patients – CRF based

Length of hospital stay

• Mean ± SD: 17 ± 4 days
  • incl pre-treatment, treatment and observation period

Reasons for non-adherence

• Premature termination of treatment N=5 (0.8%)
  • Reasons: death (3), withdrawal (1) and convulsions (1)
Results
Feasibility of implementation - Observations

Preparation of drugs
- Dilutions of infusions, tablet count / split
- Application time
  ➢ Guidelines strictly followed

Introducing catheters in veins
  ➢ Perceived as difficult
  ➢ Importance of good training of procedures (esp. paediatric)

Drug administration
- Nifurtimox: Intake observed
- Eflornithine: catheter flushing, drip rate adjustments, end of infusion

Management of adverse events
  ➢ Importance of good training of staff at all levels
Results
Confidence in treatment – Interview based

Health personnel
• NECT use considered easy
• Staff has confidence in treatment
• Guidelines considered clear and straightforward
• Staff prefers NECT over previous standard treatment
  • Especially for small children
    • Fewer catheter changes than before

Patients (sight of health personnel)
• Fear NECT less than previous standard treatment
  • Less dangerous, fewer infusions
• Like the shorter treatment period
• Many came explicit for the „new“ treatment
Results
Capacity & logistics – Interview based & observations

- Infrastructure to treat patients
  - Beds, power source, water, access to drugs and material

- Sufficient number of staff to work in 3 shifts
  - Treatment applications, management of AEs
Results

Capacity & logistics – Interview based & observations

- Sufficient storage capacities at centre, provincial and national level!
  - Treatment kits are bulky and heavy

- Adequate conditions
  - Rarely air-con, badly ventilated, limited space (drugs ordered 1-2 times/year)

- Transport to sites limiting factor
  - Boat, road condition, airplane, motorcycle

- Funds for customs and transport constrained
Conclusions & Recommendations

- Advantages over other 2\textsuperscript{nd} stage treatments
  - Melarsoprol: too toxic, painful, efficacy variable
  - Eflornithine monotherapy complex treatment schedule

- Importance of training
  - Catheter insertion and infusion techniques
  - Management of adverse events

- Logistics constraints persist
  - Storage capacity, transport & funds

- Introduction of NECT at very remote sites remains a challenge
Petra Bäumelt executed the feasibility part

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