

Swiss TPH



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Feasibility of NECT administration in rural health structures

Results from implementation in a multicentre clinical trial in the DRC

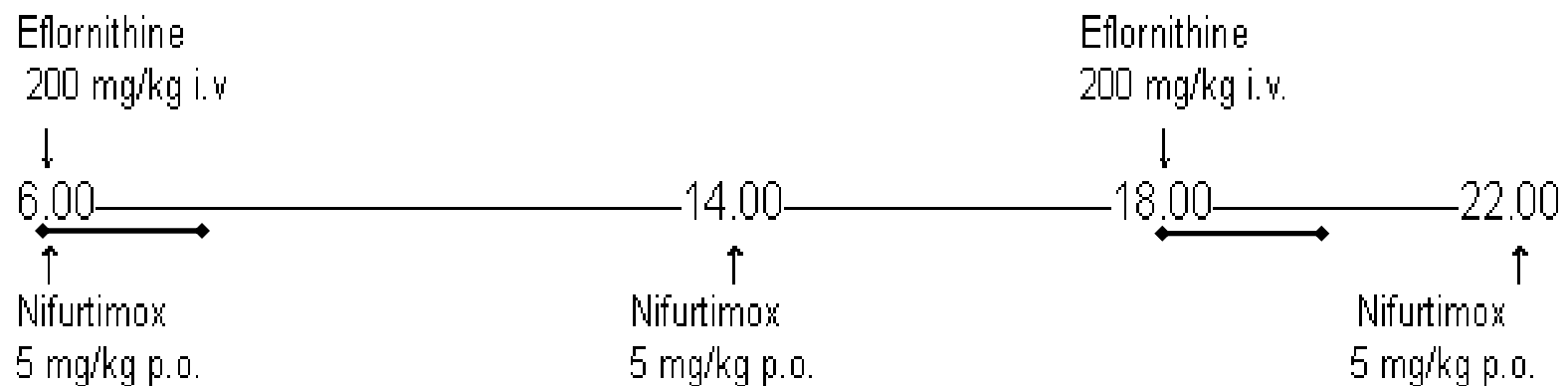
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Agenda

- 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 \pm 5%
 - Nifurtimox 98%; Eflornithine 99%



Results

Treatment adherence of patients – CRF based

Length of hospital stay

- Mean \pm SD: 17 \pm 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 2nd 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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